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Guidance for the Reregistration of Pesticide Products Containing Phosmet as the Active Ingredient

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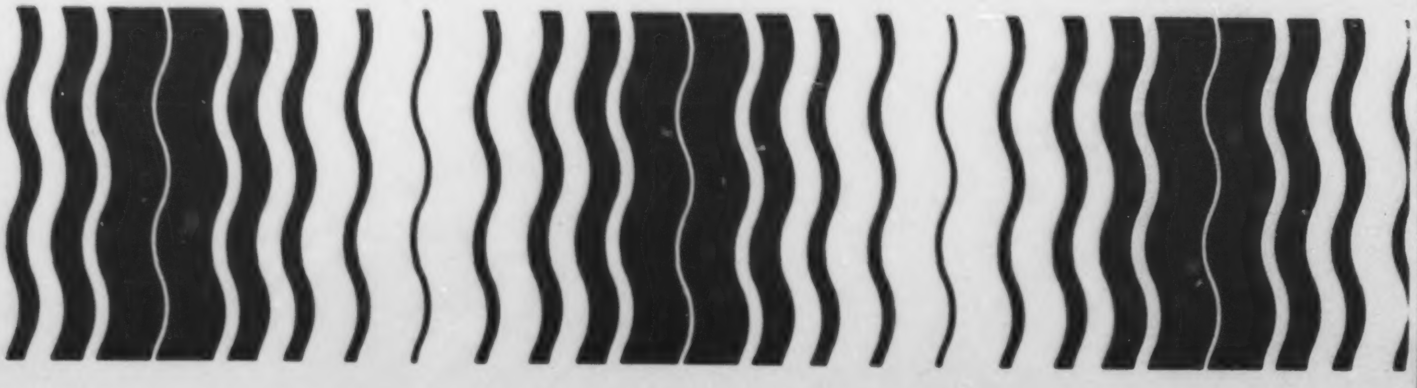

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
PHOSMET
AS THE ACTIVE INGREDIENT

CHEMICAL CODE: 059201

Case No. GS-0242

CAS REGISTRY NUMBER 732-11-6

SEPTEMBER 30, 1986

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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EPA Form 8580-	Product Specific Data Report (End-Use Products)
EPA Form 8580-	Formulator's Exemption Statement

INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme, giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review, EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and environment.

The detailed scientific review, which is not contained in this document but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. During the review of these data, however, the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. (See Section 3 - "Regulatory Position and Rationale.") Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a "Notice of Intent to Cancel" or a "Notice of Intent to Suspend" (in the case of failure to submit data).

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[1] The scientific reviews are available upon request from the Information Services Section, Room 236, CM#2, 1921 Jefferson Davis Highway, Arlington, Va. 22202 (Tel: 703-557-4453).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a Special Review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA section 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a "Notice of Intent to Suspend" the affected product registrations.

Registrants are reminded that FIFRA section 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

1. CHEMICAL COVERED BY THIS STANDARD

The Agency has conducted a review of the scientific data base on Phosmet. This section of the Registration Standard describes the chemical and its uses and concludes with a brief discussion of its registration history.

1.1 DESCRIPTION OF THE CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Phosmet

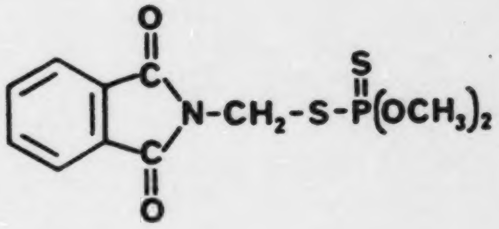
Chemical Name: N-(mercaptomethyl) phthalimide-S-(O,O-dimethyl phosphorodithioate)

Chemical Abstracts Service (CAS) Number: 732-11-6

OPP (Shaughnessy) Number: 059201

Empirical Formula: $C_{11}H_{12}NO_4PS_2$

Chemical Structure:



Trade Names: Phthalofos, PMP, Imidan, Kemolate, Prolate, R-1504, and Appa

Description of Physical Characteristics: Information listed below references the technical grade active ingredient unless' specified as the pure active ingredient (PAI).

Color: Greyish-white to white
Physical state: Crystalline solid
Odor: Typical phosphorodithioate
Boiling point: Not applicable because the technical is a solid at room temperature
Flash point: Not available in Agency files
Melting Point: 72.0°C to 72.7°C (PAI)
Solubility: 25 ppm at 20°C
Specific gravity: 1.030 at 20°C
Stability: Not available in Agency files

1.2 USE PROFILE

Phosmet is a broad-spectrum organophosphate insecticide/ acaricide. Phosmet's mode of activity involves cholinesterase inhibition, a process by which the insect is poisoned primarily by phosphorylation of acetylcholinesterase at the nerve endings. Phosmet is used for control of a wide variety of insects including the alfalfa weevil, boll weevil, codling moth, leafrollers, plum curculio, grape berrymoth, and oriental fruit moth. Phosmet is available as a 90 percent and 94 percent active ingredient technical product for formulating phosmet end-use products. Technical phosmet is produced by the Stauffer Chemical Company of Richmond, California, under the trade names Imidan Technical (90%) and Prolate Technical (94%). Prolate technical is purer than Imidan technical and is primarily used in the formulation of insecticides for control of ectoparasites on livestock and pets, and animal drugs for control of endoparasites in livestock (regulated by the Food and Drug Administration). Imidan technical is primarily used in the formulation of insecticides/ miticides for use on crop and non-crop areas. Phosmet technicals are formulated into dusts, wettable powders, impregnated resins, and emulsifiable concentrate end-use products.

The vast majority of phosmet usage (over 95 percent) is for insect control on commercial tree and vine fruit. Approximately 80 percent of the annual usage is applied to apples throughout apple production regions in the northeastern and western U.S., while 6 percent is applied to pears. The remaining 9 percent of the usage on tree and vine fruits is distributed mainly among peaches, cherries, almonds, plums, prunes, and grapes. Other sites of phosmet use include alfalfa, cotton, corn, nursery and ornamental plants and shrubs, fire ant mounds, pets and livestock. Of these sites, alfalfa usage contributes the largest annual percentage (3-4 percent). Application rates for the major crops uses (apples, alfalfa, and pears) range from 0.75 to 15 pounds active ingredient per acre depending on the type of pest and the amount of infestation.

Phosmet is applied to terrestrial food and non-food areas as a delayed dormant or foliar application with aerial or ground equipment, primarily using concentrate and semi-concentrate sprays. Livestock treatments (beef cattle and swine) are done by dusting, spraying, or dipping. Pet treatments include the use of a 5 percent dust or a 15 percent flea collar.

1.3 REGISTRATION HISTORY OF PHOSMET

The organophosphate chemicals were developed as a result of the research of Schrader in Germany just prior to World War II. However, since these compounds were intensively studied as chemical warfare agents, their development was not publicized until after the end of World War II.

Phosmet was patented by Stauffer Chemical Company in 1956 and was first registered for use in the United States by Stauffer in 1966. The formulation types currently registered include dusts (1 percent and 5 percent active ingredient), wettable powders (7.5, 12, 12.5, 50, and 70 percent active ingredient), impregnated resins (15 percent active ingredient), and emulsifiable concentrates (1 and 3 pound per gallon and 12.5 percent active ingredient).

There are 24 federal section 3 registrations (8 companies [Tobacco States Chemical Company, Stauffer Chemical Company, Robins G.& S. Company, Zoecon Industries, Aceto Chemical Company, Ford Chemical Service Incorporated, Zoecon Corporation, and Unicorn Laboratories), and 15 section 24(c) Special Local Need registrations with phosmet as the sole active ingredient. In addition there is one federally registered section 3 product containing phosmet in combination with another active ingredient (other than solvents). There are no intrastate products for phosmet.

In accordance with the Agency's ongoing Data Call-In (DCI) Program, the Agency issued three separate DCI notices on phosmet. A June 20, 1983 DCI notice requested certain chronic health effects data, while two additional notices, issued June 29, 1984 and February 28, 1985, required the submission of groundwater and reentry data respectively. The current phosmet registrations and any future applications for registration of products containing phosmet will be subject to the Agency's regulatory position as set forth in this Standard.

2. AGENCY ASSESSMENT

2.1 SUMMARY SCIENCE STATEMENT

The Agency has reviewed data submitted to support the registration of phosmet and any other pertinent data available in Agency files. As a result of this review, the Agency has determined that certain changes in the conditions of registration, including specific label restrictions and submission of missing data, are necessary to maintain current registrations of products and support registration of new products containing phosmet. A summary of these data gaps and label revisions appears in Figure 1. Note that the list contains only summary information on the data gaps and more detailed information can be obtained by referring to Table A in Appendix 1.

Based on a review of the available data the Agency has reached the following interim conclusions. A detailed discussion of the points summarized below is contained in section 2.2.

o Phosmet has been classified as a "tentative" Category C (possible human) carcinogen based on the following:

  Phosmet was associated with a significantly elevated incidence of liver tumors (adenomas, and adenomas plus carcinomas combined) in male B6C3F_1 mice at the highest dose level tested (HDT). These incidences were associated with liver hyperplastic changes and a decrease in the time to tumor occurrence. In female B6C3F_1 mice, the chemical was associated only with positive dose-related trends for liver adenomas and carcinomas.

  However, the Agency has some reservation in the classification of phosmet as a Category C oncogen. The label "tentative" Category C has been assigned until a repeat two-year rat oncogenicity study and additional mutagenicity studies are submitted and considered in conjunction with the mouse oncogenicity results.

o Phosmet has moderate to low acute oral, dermal, and eye/skin irritation toxicity. The chemical has been assigned to Toxicity Category II due to acute oral toxicity. Additional testing (acute inhalation and dermal sensitization) is required to complete the acute toxicity profile for technical phosmet. Insufficient data exist to fully assess subchronic dermal, mutagenicity, oncogenicity and the general metabolism of phosmet. Reentry data are necessary in order to establish permanent worker reentry intervals.

- Laboratory data show that phosmet is highly toxic to fish, other aquatic organisms, and bees. The use of phosmet as a miticide on apple and pear orchards, alfalfa, corn and cotton may threaten endangered aquatic organisms and two endangered insect species.

- The environmental fate data on phosmet do not meet the Agency's current testing standards. The environmental fate of phosmet is therefore largely uncharacterized and the data are inconclusive and insufficient to fully assess the fate and persistence of phosmet in groundwater and the environment.

- Phosmet is used primarily with powered spray equipment for overhead spraying in commercial tree and vine fruit and nut orchards, and spraying and dusting of livestock. Based on the potential for applicator exposure to phosmet from these uses and the lack of dermal sensitization and 21-day dermal toxicity studies, the Agency is requiring that protective clothing be worn by mixers/loaders and applicators. The Agency is also requiring a special glove permeability study.

- The Agency is requiring plant/animal metabolism and residue data to determine the nature of the residues in plant and animals, and to assure that all metabolites of concern have been identified. Also required are processing studies on apples, potatoes, plums, peaches, grapes, field corn grain, and cottonseed to more accurately assess dietary exposure.

FIGURE 1

SUMMARY OF DATA GAPS AND REQUIRED LABELING

PHOSMET

Toxicology

Acute Inhalation Toxicity (rat)
Dermal Sensitization
21 Day Dermal (rabbit)
Oncogenicity (rat)
Mutagenicity Testing
General Metabolism

Ecological Effects

Acute Toxicity to Freshwater Invertebrates (on end-use product)
Acute Toxicity to Estuarine and Marine Organisms (on end-use product)
Fish Early Life Stage and Aquatic Invertebrate Life-Cycle
Field Monitoring (avian, aquatic, and mammalian)

Environmental Fate

Hydrolysis/Photodegradation Studies
Anaerobic Soil Metabolism
Mobility Studies
Field Dissipation
Accumulation (rotational crops)
Glove Permeability
Reentry

Product Chemistry/Residue Chemistry

Product Chemistry
Plant/Livestock Metabolism
Plant/Animal Residues
Storage Stability

Labeling Revisions

Protective Clothing
Reentry Restriction
Fish and Wildlife Toxicity Warnings
Endangered Species Warnings
Domestic Pet Warnings

2.2 PRELIMINARY SCIENCE FINDINGS

This subsection summarizes the results of studies and reports to the Agency relating to the acute and chronic toxicity of phosmet.

2.2.1 ACUTE TOXICITY

Acute toxicity studies submitted in support of the registration of phosmet technical satisfy the data requirements for acute oral and dermal toxicity, primary eye and dermal irritation, and acute delayed neurotoxicity. Phosmet, like other organophosphates, can be absorbed by inhalation and skin penetration. The extent of dermal absorption may be slight however, as evidenced from the low toxicity by the dermal route. Signs of acute intoxication to exposure are primarily related to cholinesterase inhibition and include headache, dizziness, weakness, loss of coordination, nausea and respiratory depression.

The acute inhalation and 21-day dermal studies are not acceptable and must be repeated. There are no studies available on the dermal sensitization potential of phosmet therefore this test data must be submitted.

Acute oral toxicity: The acute oral LD_{50} (lethal dose) of technical phosmet in rats has been reported in several studies to range from 113 milligrams (mg) per kilogram (kg) to 304 mg/kg. The acute oral LD_{50} of technical phosmet in mice in two studies ranged from 38 mg/kg to 50.1 mg/kg. The Agency has assigned phosmet to Toxicity Category II (moderately toxic by the oral route of exposure) based on the results of studies conducted in the rat because the rat is the preferred test species.

Acute dermal toxicity: The acute dermal LD_{50} of technical phosmet in rabbits has been reported in three separate studies to be greater than 3,160 mg/kg. The Agency has assigned phosmet to Toxicity Category III (mildly toxic by the dermal route of exposure) based on the results of the above studies. All three of these studies together satisfy the requirement for an acute dermal toxicity study.

Acute inhalation toxicity: The acute inhalation LCt_{50} (lethal concentration) in rats has been reported to be greater than 0.152 milligrams per liter (mg/l) after exposure for four hours. The study was considered unacceptable because technical phosmet should have been tested at multiple dose levels in the form of particulate matter as opposed to the single dose level of phosmet in vapor form. The appropriate toxicity category could not be determined since no deaths occurred at the one level tested. A repeat acute inhalation toxicity study must be submitted.

Primary eye irritation: The Agency reviewed two primary eye irritation studies. In one study technical phosmet produced mild redness when instilled in the unwashed eyes of three rabbits at 24 hours after exposure. The eyes returned to normal within 7 days. In the other study phosmet produced corneal opacity, redness, chemosis, and discharge in 1 of 3 rabbits. The irritation was reversible within 7 days. The Agency has assigned phosmet to Toxicity Category III (mild irritation) based on these results. The two studies together satisfy the requirement for a primary eye irritation study.

Primary dermal irritation: In a study using six albino rabbits technical phosmet produced no irritation when applied to intact or abraded skin on the backs of the rabbits (non-irritant). The Agency has assigned phosmet to Toxicity Category IV for primary dermal irritation based on these results. This study meets the Agency requirement for a primary dermal irritation study.

Acute delayed neurotoxicity: The Agency reviewed four studies in which technical phosmet was tested for its potential for causing delayed neurotoxicity. In one study phosmet, administered to White Leghorn hens at levels up to 1000 parts per million (ppm) for six weeks, failed to produce delayed neurotoxicity. In a second study phosmet administered to unspecified "birds" at levels up to 1,413 mg/kg (2 doses separated by a 3 week observation interval) failed to produce delayed neurotoxicity. In a third study questionable positive effects were observed at a level of 60 mg/kg. Due to the contradicting evaluations of clinical signs and/or histopathological data by several authors of the report, it was decided to repeat the study. A fourth study was conducted in which no delayed neurotoxic effects were observed in adult hens administered phosmet at levels up to 2,050 mg/kg, however body weight, food consumption, and egg production were significantly decreased in the 2,050 mg/kg test group. Based upon these results, which together meet the requirements for an acute delayed neurotoxicity study, the Agency has determined that phosmet is not a delayed neurotoxin.

2.2.2 SUBCHRONIC TOXICITY (ORAL)

Although subchronic oral toxicity studies were conducted in the dog and rat they were not evaluated since the chronic feeding studies satisfy the requirement for a subchronic feeding study.

21-day repeated dose dermal toxicity: A repeated dose dermal reproduction study has been conducted on phosmet technical under the context of conducting an oral/dermal one-generation reproduction study. Rabbits were administered phosmet either by the oral or dermal route. Cholinesterase depression ranged from slight to marked depending on the dose level, and some local dermal effects (hyperkeratosis) were noted. A NOEL was not demonstrated for cholinesterase inhibition. A 21-day dermal toxicity study was conducted in rabbits with Imidan 50-W and Imidan 3-E but again NOELs could not be established. A second series of 21-day dermal toxicity studies were conducted with Imidan 50-W and Imidan 3-E, again, however, NOELs could not be determined. The studies do not satisfy the requirement for a repeated-dose dermal toxicity study. These data are being required.

2.2.3 ONCOGENICITY STUDIES

Rat: Phosmet was administered in the diet to 25 Charles River strain albino rats/sex/dose level at doses of 0, 20, 40, and 400 parts per million (ppm) for 2 years. The study was conducted by Stauffer Chemical Company in the 1960's. No tumors were observed that were considered to be related to treatment with phosmet. However, there appeared to be a large proportion of rats sacrificed at the end of the study in the mid and/or high dose groups that showed the presence of pituitary adenomas and thyroid adenomas. The incidences of pituitary adenomas were a) Males: 3/10 or 30%, control; 1/10 or 10%, low dose; 6/10 or 60%, mid dose; and 4/7 or 57%, high dose; and b) females 6/17 or 35%, controls; 3/13 or 23%, low dose; 5/10 or 50%, mid-dose; and 6/12 or 50%, high dose. The incidences of thyroid adenomas were a) Males: 0/13 or 0%, controls; 0/13 or 0%, low dose; 2/13 or 15%, mid dose; and 2/14 or 14%, high dose; and Females: 1/19 or 5%, controls; 2/14 or 14%, low dose; 0/19 or 0%; mid dose; and 2/16 or 13%, high dose. The Agency recognized that the number of animals sacrificed at the end of the study were too small to fully evaluate these tumor responses. In addition, although the study might be considered acceptable according to criteria for studies conducted many years ago, it is inadequate according to modern standards in terms of the number of surviving animals available for gross and histopathological examination.

In addition, the limited data available for this study made it difficult to determine whether or not a maximum tolerated dose (MTD) was tested. The toxicological effects that were reported at the highest dose level tested, i.e., 400 ppm, included 1) decreases in plasma, brain and erythrocyte cholinesterase levels of greater than 20% (the Agency recognizes that changes of ± 20% in these parameters are common based on experimental technique), 2) weight loss ranging from 13% to 17% in males and 0% to 10% in females at various intervals during the study, and 3) "moderate" liver cell vacuolation. Based on these data, it was determined that the mid dose level, i.e., 40 ppm, was a NOEL, for chronic effects (other than oncogenicity) and that the highest dose level tested, i.e., 400 ppm, may have been close to a MTD level. In order to resolve the issue of the potential oncogenicity of phosmet a repeat oncogenicity study in rats is required.

Mouse: Phosmet was administered in the diet to 60 $B6C3F_1$ mice/sex/dose level at doses of 0, 5, 25 and 100 ppm for 2 years. Ten mice/sex/dose group underwent interim sacrifice at 12 months after the start of the study. The study was conducted by Stauffer Chemical Company between April 1981 and May 1983. The following chart outlines the incidence patterns of liver tumors in male and female mice suggestive of a compound related effect.

Mouse Oncogenicity Data

Liver Tumor Type & Observation Time	Sex	Dose (ppm)			
		0	5	25	100
Interim Sacrifice[a]					
Adenoma	M	0/10(0%)	1/10(10%)	1/10(10%)	2/10(20%)
Carcinoma	M	0/10(0%)	0/10(0%)	1/10(10%)	1/10(10%)
Combined	M	0/10(0%)	0/10(0%)	2/10(20%)	3/10(30%)
Final Kill[b]					
Adenoma	M	9/49(18%)	9/50(18%)	11/50(20%)	19/50(38%)T*
Carcinoma	M	14/49(24%)	11/50(20%)	10/50(22%)	13/50(26%)
Combined	M	23/49(47%)	20/50(40%)	21/50(42%)	32/50(64%)T
Total (Interim Sacrifice & Final Kill)					
Adenoma	M	9/59(15%)	10/60(17%)	12/60(20%)	21/60(35%)T*
Carcinoma	M	14/59(24%)	11/60(18%)	11/60(18%)	14/60(23%)
Combined	M	23/59(39%)	21/60(35%)	23/60(38%)	35/60(58%)T*
Final Kill[b]					
Adenoma	F	5/48(10%)	4/50(8%)	5/48(10%)	9/50(18%)T
Carcinoma	F	5/48(10%)	4/50(8%)	3/48(6%)	9/50(18%)T
Combined	F	10/48(20%)	8/50(16%)	8/48(16%)	18/50(36%)T
Total (Interim[c] Sacrifice & Final Kill					
Adenoma	F	5/58(9%)	4/60(7%)	5/58(9%)	9/60(15%)
Carcinoma	F	5/58(9%)	4/60(7%)	3/58(5%)	9/60(15%)
Combined	F	10/58(18%)	8/60(14%)	8/58(14%)	18/60(30%)

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a = Interim sacrifice values were obtained at study week 52 for 10 mice/sex/dose level.

b = Final kill values include mice sacrificed at study week 104 plus all intercurrent deaths occurring after study week 52.

c = Total values include interim sacrifice value plus final kill and intercurrent deaths occurring after study week 52.

T = Significant ($p < 0.05$) positive dose-related trend using Cochran-Armitage Trend Test.

* = $p < 0.05$ compared to controls using Fisher-Exact Test.

An elevated incidence of liver tumors was observed in both male and female $B6C3F_1$ mice. In the male mice, tumors were observed both at the interim kill period (52 weeks) and at the time of the final sacrifice (104 weeks). At the interim kill period, there was a statistically significant ($p<0.05$) positive trend for adenomas/carcinomas combined. In addition, at the final sacrifice period, there were statistically significant ($p<0.05$) positive trends for adenomas per se, and for adenomas/carcinomas combined. The incidence of adenomas was also significantly ($p<0.05$) elevated in high dose male mice, whereas the incidence of carcinomas was not increased. When the total number of animals for which tissues were histologically examined at interim sacrifice plus the final kill period were evaluated, there were also statistically significant ($p<0.05$) positive trends for adenomas per se, and for adenomas/carcinomas combined. The incidences of adenomas per se, and adenomas/carcinomas combined, were also significantly ($p<0.05$) elevated in high dose male mice. In addition, there was evidence for liver hyperplasia in the high dose males as indicated by the appearance of clear cell foci both at interim sacrifice (0% controls, 0% low dose, 0% mid dose, and 10% high dose) and at final sacrifice (8% controls, 12% low dose, 10% mid dose, and 26% high dose). In the female mice positive trends for tumors were observed only at the time of final sacrifice (104 weeks) but not at the interim kill period (52 weeks). At the final sacrifice period, there were statistically significant ($p<0.05$) positive trends for adenomas per se, carcinomas per se, and for adenomas/carcinomas combined. However, none of these individual tumor types were significantly elevated in high dose female mice. Finally, results similar to these were obtained in female mice when the total number of animals for which tissues were histologically examined in the study at interim sacrifice plus the final kill period were evaluated. Although, there was some indication of liver hyperplasia in females at interim sacrifice when no tumors occurred (i.e., clear cell foci occurred in 0% of control, 0% low dose, 9% mid dose, and 20% high dose females), there were no clear cell foci observed in female livers at the final sacrifice period when positive trend tumors were noted.

In summary, phosmet produced an increase in heptocellular adenomas (also reflected as an increase in the incidence of adenomas/carcinomas combined) at the highest dose level tested (100 ppm) in male mice. No significant increase in carcinomas occurred, indicating that there was no clear trend of progression of benign tumors progressing to malignancy. However, there was evidence for liver hyperplasia in male mice. There was also an indication from the interim sacrifice results that the liver tumors occurred in male mice with a reduced latency. Phosmet also produced positive trends for adenomas, carcinomas, and both tumor types combined, in female mice, but none of these tumors were significantly elevated at the highest dose level tested (100 ppm), there was no hyperplasia, and no indication that the tumors occurred with a reduced latency period.

The phosmet liver tumor data were compared with historical control tumor data from the National Toxicology Program (NTP) data base (Goodman et. al., Handbook of Carcinogen Testing, pg. 291, 1985). For male mice the comparison indicated that at the time of the final kill, the increased incidences of adenomas (38%) and adenomas/ carcinomas combined (64%) seen in high dose male mice exceeded the historical range of these tumor types seen in the NTP studies (i.e., range of 0-24% for adenomas, and range of 16-58% for adenomas/carcinomas combined). For female mice the comparison indicated that at the time of the final kill, the increased incidences of carcinomas (18%) and adenomas/ carcinomas combined (36%) seen in high dose female mice exceeded the historical range of tumor types seen in the NTP studies (i.e., range of 0-15% for carcinomas, and range of 0-20% for adenomas/carcinomas). Historical data available from a single study in B6C3F$_1$ mice conducted at Stauffer Chemical Company, was of limited use because only average tumor values not range data were available.

In the chronic mouse bioassay, the highest dose (i.e., 100 ppm) tested appeared to approximate a MTD level in both males and females. The effects seen at this dose included: a) reductions of plasma and brain cholinesterase activity and increases in liver weight in both male and females; b) microscopic pathological changes in the livers of male mice (degeneration and vacuolation of individual cells and foci of eosinophilic cells) and in female mice (mid zonal degenerative vacuolation, necrotizing inflammation, and cell necrosis of individual liver cells); c) convulsions, stomach mucosal hyperplasia, testicular atrophy, and perivasculitis of muscle in males; and d) inflammation of the stomach and duodenum and myometrial atrophy of the uterus in females.

Additional Data Utilized in the Evaluation of Oncogenic Effects:

Two year dog toxicity study: A 2-year study of phosmet was conducted in purebred beagles. The chemical was administered in the diet to 3 dogs/sex/dose level at doses of 0, 20, 40 and 400 ppm. This NOEL was 40 ppm. The LEL (lowest effect level) was 400 ppm based upon the finding of brain and erythrocyte cholinesterase inhibition. No unusual target organ effects were noted.

Metabolism studies: Three similar metabolism studies were performed in which single oral doses of ^{14}-C phosmet (doses ranging from 19 to 31 milligrams per kilogram (mg/kg) were administered to Long-Evans rats. The animals were sacrificed 3 to 5 days after dosing. Absorption from the GI tract appeared to be rapid and fairly complete. After 72 to 96 hours, approximately 78-79% of the administered radioactivity (RA) was eliminated in the urine and approximately 18-19% of the RA was eliminated in the feces. The major water soluble urinary metabolites have been tentatively identifed as phthalamic acid (51-54%), phthalic acid (16-21%), and a derivative of phthalic acid (7-9%). The major water soluble metabolite tentatively identified in the feces was phthalamic acid. No unchanged phosmet was found in the urine. Less than 0.04% of the RA was eliminated as CO_2. Tissue residues accounted for 2.6 to 3.5% of the administered RA. There does not appear to be any selective localization of RA in any tissue. These data are not considered acceptable under current standards because more rigorous methods should have been used to identify the metabolites and more details included to justify the results.

Mutagenicity assays: Phosmet was evaluated in several mutagenicity tests. The chemical was found to be positive only when tested in *S. typhimurium* strain TA-100 without metabolic activation. In contrast, the chemical was found to be negative in all other tests. These tests included tests with *S. typhimurium* strains TA-98, TA-1535, TA-1537 and TA-1538 with and without metabolic activation, *S. typhimurium* strain TA-100 with metabolic activation, and a reversion assay with *E. coli* strains B/r WP2 hcr$^+$ and WP2 hcr$^-$ and a rec$^-$ assay with *B. subtilis* H17 Rec$^+$ and M45 Rec$^-$ without metabolic activation. No mutagenicity study of phosmet was performed in mammalian cells in culture.

Reproduction and teratology studies: Data from several reproduction/teratology studies were considered. In a 3-generation reproduction study in rats, no adverse reproductive effects occurred at the highest dose tested (HDT) 80 ppm. In a one-generation reproductive/teratology study in rabbits, no adverse reproductive or teratological effects occurred at the HDT (60 mg/kg). In four other teratology studies performed in monkeys, rats (2 studies), and rabbits, no teratologic effects were noted at HDT levels ranging from 8 to 35 mg/kg.

Structure-activity considerations: Phosmet contains the mercaptomethylphthalimide moiety as its primary structural configuration. A computer based search on the Chemical Information System (CIS) generated a list of 16 additional chemicals that also contained this moiety. A literature search conducted over several National Library of Medicine databases failed to uncover any studies to indicate that any of the 16 chemicals are carcinogenic or mutagenic. Phosmet is also structurally similar to folpet, which contains the phthalamide moiety, and is known to produce intestinal tumors in mice and to be mutagenic in in vitro systems. However, folpet, unlike phosmet, contains a side chain which is thought to convert to thiophosgene, a highly reactive chemical believed to be responsible for producing intestinal tumors in mice.

Weight of Evidence Considerations for Oncogenicity:

The following facts were considered to be important in a weight of evidence determination of oncogenic potential and classification of phosmet.

1. In male B_6C_3F1 mice, phosmet produced a significantly elevated incidence of heptocellular adenomas (also reflected as an increase at the highest dose tested (i.e., 100 ppm). The adenomas occurred with a reduced latency, were associated with evidence of liver hyperplasia, and exceeded National Toxicology Program (NTP) historical control incidences, but did not progress to carcinomas.

2. Phosmet was associated with significant positive dose-related trends for liver adenomas and for liver carcinomas in female $B6C3F_1$ mice. The incidence of tumors was not significantly elevated at the highest dose tested, did not occur with a reduced latency, and was not associated with liver hyperplastic changes. However, the carcinomas (but not the adenomas) did exceed the NTP historical incidence for carcinomas.

3. The highest dose tested (100 ppm in the diet) in the chronic mouse bioassay appeared to be approximately a maximum tolerated dose (MTD) in both males and females.

4. Phosmet was reported to be not oncogenic when administered in the diet to Charles River albino rats at doses ranging from 20 to 400 ppm. This test however was not considered to be an acceptable negative study by present day standards due to the fact that only very small numbers of animals were histopathologically evaluated after 2 years.

5. Phosmet was tested for mutagenicity in a series of in vitro microbial assays. A positive mutagenic response was obtained only in one bacterial strain (S. typhimurium TA-100) whereas negative results occurred in tests in several other procaryote strains (S. typhimurium TA-1535, TA-1537, TA-1538, and TA-98; E. coli B/W WPs hcr$^+$ and WP2 hcr$^-$; and B. subtilis H17 Rec$^\mp$ and M45 Rec$^-$). The

battery of mutagenicity studies performed on phosmet was limited and additional studies must be performed (e.g., mammalian cells in culture).

6. Metabolism data for phosmet in Long-Evans rats indicated that phosmet, which is a lipophilic molecule, was rapidly absorbed, metabolized, and excreted primarily in the urine. The major metabolites identified in urine and/or feces were phthalamic and phthalic acids. No unusual tissue localization of the compound occurred. These data however were not considered acceptable under current standards due to the fact that more rigorous methods should have been used to identify the metabolites and more details included to justify the results.

7. No teratogenic effects were reported for phosmet in oral teratology studies in monkeys, rats, and rabbits. The compound has no adverse reproductive performance effects in oral reproduction studies in rats and rabbits.

8. Sixteen structural analogues of phosmet were identified following a computerized data base search using the Chemical Information System (CIS). No carcinogenity or mutagenicity studies were performed on any of these analogues according to a National Library of Medicine data base literature search. Phosmet is also structurally similar to folpet, a known oncogen (intestinal tumors) and mutagen in mice. The oncogenicity of folpet is thought to be due to conversion of its side chain to thiophosgene; this side chain is not present in phosmet.

Based upon the above "weight of evidence" considerations and the criteria* contained in the proposed Guidelines for Carcinogen Risk Assessment (Federal Register Notice of

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* These guidelines categorize the evidence on carcinogenicity of chemicals in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, Group A, "Human Carcinogen", is reserved for those chemicals for which there is sufficient evidence of carcinogenicity from human epidemiological studies. Group B, "Probable Human Carcinogen," is divided into subgroups 1 and 2. Group B1 requires some human epidemiological evidence. Group B2 is said to be an appropriate categorization if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. "Sufficient evidence" is defined as an increased incidence of malignant tumors (or combined malignant and benign tumors) -- (a) in multiple species or strains, (b) in multiple experiments, or (c) to an unusual degree with regard to incidence, site or type of tumor, or age of onset. Group C, "possible human carcinogen," is said to be appropriate if there is, among other things, "definite malignant tumor response in a single well conducted experiment"; that is, "limited evidence" from animal studies. (There is also a Group D, "Not Classified," and a Group E that is reserved for chemicals shown to be non-carcinogenic in animal and/or human studies.

November 23, 1984 - 49 FR 46294) the Agency concluded that there was limited evidence of phosmet's carcinogenicity and phosmet should be classified as a Category C (possible human) carcinogen. The Agency has some reservation in the classification of phosmet as a Category C oncogen because of the lack of an acceptable oncogenicity study in a second rodent species and acceptable mutagenicity data. Therefore, the label "tentative" Category C has been assigned until a repeat two-year rat oncogenicity study and additional mutagenicity studies are submitted and considered in conjunction with the mouse oncogenicity study.

2.2.4 CHRONIC EFFECTS (NON-ONCOGENIC)

Rat: The oncogenicity study described above also served as a chronic feeding study because it provided results on non-oncogenic effects in addition to oncogenic effects. Details of this study are presented under "Oncogenicity" above. The Agency concluded that this combined chronic feeding/oncogenicity study satisfied the requirement for a chronic feeding study in rats. The study results indicated a NOEL of 40 ppm for chronic effects other than oncogenic.

Non-rodent (dog): The Agency has reviewed a non-rodent chronic feeding study in which beagle dogs were administered technical phosmet in the diet at levels of 0, 20, 40, and 400 ppm for 2 years. Erythrocyte and brain cholinesterase activity was inhibited at the 400 ppm level. The "no observable effect level" (NOEL) was demonstrated to be 40 ppm. The Agency considers this study to have satisfied the requirement for a chronic non-rodent feeding study.

Mutagenicity: A dominant lethal ("embryotoxicity") study was conducted in the rabbit, however, insufficient information was available to assess the results of the study. The requirements for mutagenicity studies have not been satisfied.

Metabolism: The results of three metabolism studies indicate that phosmet is rapidly eliminated with 78 percent excreted in the urine and 19 percent in the feces within 72 hours after administration of a single oral dose to rats. The major water soluble urinary metabolites have been "tentatively" identified as phthalamic acid (51 to 54%), phthalic acid (16 to 21%), and a derivative of phthalic acid (7 to 9%). The major water soluble metabolite "tentatively" identified in the feces was phthalmic acid. The requirement for a metabolism study has not been satisfied because the methods employed to identify the metabolites lacked sufficient detail to confirm/validate the results reported.

Teratogenicity - rabbit: In a one-generation teratology study technical phosmet was fed and dermally applied to New Zealand White rabbits at dose levels of 0, 10, 30, and 60 mg/kg for three weeks prior to and during the 18 days following mating. Weight gain was decreased in animals fed 60 mg/kg. Cholinesterase depression ranged from slight to marked in the 3 oral dose groups. No teratogenic effects were noted at the 60 mg/kg dose, which was the highest dose tested (HDT). The teratogenic NOEL was determined to be 60 mg/kg.

Teratogenicity - monkey: In this study phosmet was administered to monkeys (*Macaca mulatta*) at levels of 2.0, 4.0, and 8.0 mg/kg from day 22 through 32 of gestation. Pregnancy was terminated on the 84th day of gestation. Administration of phosmet did not produce teratogenic effects at the HDT. The teratogenic NOEL was demonstrated to be 8.0 mg/kg. Although the highest dose level tested in this study was low when compared with the rodent dose levels, the Agency concluded that because the monkey is more closely related to humans than rodents the dosing used here was adequate to assess the teratogenic effects. The study satisfies the requirement for a teratogenicity study in a second species.

Reproductive effects - rodents: In a three-generation reproduction study technical phosmet was administered to F_0 Charles River albino rats in the diet at a level of 40 ppm. After production of F_1 litters, the pups (F_{1b}) received either 40 or 80 ppm doses of phosmet. This dosing regimen was maintained through the production of the third generation. No reproductive effects from the administration of phosmet were observed. The reproductive NOEL was determined to be 80 ppm. This study satifies the requirement for a reproductive study.

2.3 OTHER SCIENCE FINDINGS

2.3.1 ECOLOGICAL CHARACTERISTICS

This subsection summarizes the toxicity of phosmet to fish and wildlife.

Avian species: The data base used to assess the acute and subacute toxicity of phosmet to birds is complete. Phosmet is practically non-toxic to slightly toxic to birds. The acute oral LD_{50} for the technical grade material was determined to be 2009 mg/kg. Subacute dietary LC_{50}'s (lethal concentration) of 501 ppm, 3146 ppm, and >5000 ppm were determined for bobwhite quail, ring-necked pheasant, and mallard ducks, respectively, for technical phosmet. Residues on avian feed items, immediately after application at maximum application rates (eg. apple orchards, the most common use), are expected to approximate 90 ppm. Therefore, residues on avian food items immediately following applications of phosmet at maximum rates are not expected to produce lethal poisonings, given phosmet's low systemic toxicity.

In regard to chronic effects, the level of phosmet in the feed which produces no reproductive impairment is between 60 and 150 ppm for bobwhite quail and between 25 and 60 ppm for mallards. The expected residue levels on avian food items noted above, if maintained over the course of the breeding season (which is possible since phosmet use patterns call for repeated application), may be sufficient to produce reproductive impairment.

Therefore the Agency is requiring actual residue monitoring of avian feed items from the use of phosmet on apples, corn, cotton, and alfalfa to complete an evaluation of the reproductive hazard.

Mammals: The toxicity of phosmet to mammals is low (rat LD_{50} = 113 to 304 mg/kg), therefore it is unlikely that mammals would be killed by a single application. The reproductive NOEL for rats is 80 ppm. Similar to birds, mammals such as rabbits, may be exposed to residues causing reproductive effects when phosmet is applied to alfalfa and orchards.

The Agency is requiring actual residue monitoring of mammalian feed items from alfalfa and orchard use to complete an evaluation of the reproductive hazards to mammals.

Insects: Studies indicate that phosmet is highly toxic to honeybees and displays extended residual toxicity. Due to its high toxicity, precautionary labeling is being required for phosmet products intended for foliar application. The labeling statement will instruct the user not to apply the product when there is bee activity at the treatment site.

Aquatic species: Based upon laboratory data the Agency has characterized phosmet as very highly toxic to warmwater fish and highly toxic to coldwater fish. The chemical is also very highly toxic to aquatic and estuarine invertebrates. Acute 96-hour LC_{50}'s of 230 parts per billion (ppb) for rainbow trout and 70 ppb for bluegill sunfish have been determined for technical phosmet. A 48-hour EC_{50} (effective concentration) of 5.6 ppb was determined for *Daphnia magna* exposed to technical phosmet. Acute 96-hour LC_{50} of 4.2 and 2.0 ppb were determined for *Gammarus fasciatus*. Terrestrial residue analysis and aquatic runoff modeling indicates further that certain use patterns of phosmet could result in exposure of certain aquatic organisms to potentially hazardous levels of the pesticide.

Because of the potential toxicity of phosmet to aquatic species, the Agency is concerned about the direct and indirect hazards posed to the aquatic environment by repeated crop applications of phosmet. Those terrestrial food crop uses where aquatic contamination is of primary concern are corn, alfalfa, cotton, and citrus where drift, runoff, and soil erosion of phosmet to lakes, streams, ponds, other bodies of water, and wetlands may occur. Because of these aquatic contamination concerns, the Agency is requiring precautionary labeling for aquatic organisms. In addition, the Agency is requiring additional acute and chronic fish and invertebrate tests and field monitoring to evaluate the potential toxicity to these organisms from terrestrial crop applications that may result in aquatic contamination.

Endangered species: Hazards to endangered species posed by phosmet use on corn, cotton and other food uses have been examined. In addition, informal consultations between EPA and the Office of Endangered Species (OES) have raised concerns about the hazards to endangered species, primarily aquatic species, from phosmet use on apples, pears, corn, cotton, and alfalfa. Considering the high toxicity of phosmet to aquatic organisms, the potential for aquatic contamination from terrestrial crop applications and information obtained from consultations with OES, the Agency has determined that endangered species in the vicinity of apple and pear orchards, alfalfa, corn and cotton crops, could be placed at risk. Also, two endangered insect species in the vicinity of food crop uses of phosmet in certain counties of California could also be threatened. Therefore, labeling statements prohibiting the use of phosmet in certain areas will be necessary.

2.3.2 ENVIRONMENTAL FATE AND GROUND WATER

Phosmet is not expected to be persistent in the environment because preliminary data indicates a relatively short half-life ($\leq$ 11 days). However, there are many data gaps in the area of environmental fate which precludes a complete assessment of the environmental fate for this chemical. Because of its physical-chemical properties, there is the potential for phosmet and possibly its degradates to contaminate ground water in some soils. The Agency requested submission of basic ground water data on June 29, 1984, under the ground water Data Call-In notice. Several studies were submitted/referenced in response to the call-in, but these data were not fully acceptable or in all cases representative of the actual environmental conditions. Thus, the Agency is requiring the full complement of basic groundwater studies.

Preliminary data indicate several trends of phosmet behavior in the environment. Radio-labeled phosmet degraded on irradiated silica gel TLC plates, with a half-life of approximately 3-8 days. Sterilization of loam and loamy sand soils increased the half-lives to approximately 4.5 and 12.2 days respectively, and drying the loam soil increased the half-life to approximately 19 days, indicating that microbial degradation is a factor in the degradation of this compound. The major degradates observed were phthalamide, N-methoxymethyl phthalimide, phthalic acid and N-hydroxymethyl phthalamic acid. Phosmet appears to be moderately mobile to immobile in soils ranging in texture from sand to silty clay loam. Mobility in soils is inversely correlated with organic matter content and soil pH. In the field phosmet dissipated in sand and sandy loam soils with a half-life of 1-11 days. To fully assess and complete the environmental fate profile of phosmet, the Agency is requiring hydrolysis, soil dissipation, anaerobic soil metabolism, leaching, photodegradation, rotational crop and re-entry data.

2.3.3 REPORTED PESTICIDE INCIDENTS

Under section 6(a)(2) of FIFRA a registrant is required to submit adverse effects data to EPA. The Agency has reviewed a summary of reports of adverse effects incidents (primarily adverse animal reactions submitted by the registrant) regarding the use of a phosmet flea and tick dip formulation (Paramite) on dogs and cats. Although this product is sold primarily to veterinarians, it is also available to homeowners through veterinarians.

The summary report included 67 incidents involving this product in the period June 1978 through September 21, 1979. Of these 67 incidents, 39 involved cats only, 16 involved dogs only, 2 involved cats and dogs, 8 involved human reactions, and 2 involved dogs and human reactions. Reported mortalities from these incidents were 20 cats (one leukemic) and 12 dogs.

In 1979, in response to reports of adverse reactions and deaths to house cats from the use of this product in the Austin, Texas area, the Agency conducted a survey of veterinarians in that area. Veterinarians were contacted by the Texas Epidemiological Studies Program, Texas Tech University School of Medicine, to ascertain their experiences or awareness of problems involving Paramite on pets. Out of 14 veterinarians contacted, 8 reported problems, 5 experienced no difficulty with its use, and 1 did not use Paramite. Several expressed the opinion that the material is probably not being used properly in those cases where problems occur. Since the summary report and telephone survey in 1979, the Agency has received additional complaints from pet owners regarding adverse reactions on pets.

2.4 TOLERANCE REASSESSMENT

Tolerances have been established on a number of raw agricultural commodities and in meat, fat and meat byproducts (40 CFR 180.261) and in processed food (21 CFR 193.279) for phosmet and its oxygen analog at levels ranging from 0.1 to 40.0 ppm. A listing of the established tolerances is located at the end of this section.

The Agency has evaluated the residue and toxicology data supporting these tolerances and reviewed all uses of phosmet. Based on the available data the Agency has reached the following conclusions:

2.4.1 RESIDUE DATA

EPA has evaluated the residue data supporting the existing tolerances and has determined that the metabolism of phosmet in plants and animals is not adequately understood and that residue data on certain crops are inadequate.

Below is a brief summary outlining the acceptable residue data supporting established tolerances, additional data necessary to reassess tolerances, and revisions necessary in the current tolerance expressions for certain commodities. It should be noted that the adequacy of established tolerances may change after information on the nature of the residues in plants and animals is submitted and evaluated.

o Sufficient data are available to ascertain the adequacy of established tolerances for residues of phosmet in or on tomatoes, pears, apples, peaches, cherries, blueberries, cranberries, almond hulls, sweet corn (kernels plus cob with husks removed), field corn, corn forage and fodder, alfalfa, cottonseed and kiwi. Insufficient crop data are available to ascertain the adequacy of the established tolerances for residues in or on potatoes, peas, pea forage, pea hay, citrus fruits, apricots, nectarines, plums, tree nuts, and cottonseed oil. The tolerance for residues in or on sweet potatoes must be revised.

o Tolerances for residues in animal commodities cannot be assessed at this time until the required animal metabolism studies and all studies regarding the magnitude of residues in or on feed items have been submitted and reviewed.

o Processing studies are required for potatoes, apples, plums, peaches, grapes, field corn grain, and cottonseed. Data on the fate of residues after cooking and washing of apples and peaches must also be submitted.

o In addition to the conclusions stated above regarding the adequacy of established tolerances, the Agency has made the following administrative determinations: a) the tolerance definition for "cherries" will be amended to "cherries sour"; (b) the tolerance definition for "alfalfa" will be changed to "alfalfa hay and forage"; (c) a food additive tolerance must be proposed for residues in citrus oil since data indicate that residues may concentrate up to 4X after processing (this tolerance proposal is contingent upon the final oncogenicity classification for phosmet - see footnote page 33). (d) the tolerance for residues in or on alfalfa forage will be reduced from 40 to 20 ppm since residue data indicate 20 ppm is adequate (the tolerance for residues in or on hay should remain at 40 ppm); (e) a crop group tolerance of 10 ppm may be proposed for residues in or on members of the pome fruits group; and (f) the established tolerance for residues in or on cranberries will be revoked because there are currently no registered uses for this crop.

2.4.2 TOXICOLOGY DATA AND ACCEPTABLE DAILY INTAKE (ADI)

The toxicology data base considered in support of the tolerances and the ADI includes:

STUDY TYPE	RESULT
2-Year Chronic Feeding/rat	Systemic NOEL = 40 ppm
2-Year Chronic Feeding/dog	Cholinesterase NOEL = 40 ppm
3-Generation Reproduction/rat	NOEL = 80 ppm
Teratology Study/rabbit	Negative @ 60 mg/kg/day
Teratology Study/monkey	Negative @ 8 mg/kg/day

Refer to section 2.2 for specific details regarding these studies.

The Acceptable Daily Intake (ADI) and the Maximum Permissible Intake (MPI) are two ways of expressing the amount of substance that the Agency believes, on the basis of the results of data from animal studies and the application of "safety" or "uncertainty" factors, may safely be ingested by humans without risk of non-oncogenic adverse health effects. The ADI is expressed in terms of milligrams (mg) of the substance per kilogram (kg) of body weight per day (mg/kg/day). The MPI, a related figure, is obtained by assuming a human body weight of 60 kg, and is expressed in terms of mg of substance per day (mg/day). It was determined that the rat is the most sensitive species to phosmet. Therefore the ADI for humans was based on the 2-year chronic feeding study in rats. The ADI in humans was calculated to be 0.02 mg/kg/day and the maximum permitted intake (MPI) equal to 1.2 mg/day with a NOEL of 40 ppm and a safety factor of 100.

This ADI represents a revision to the previously calculated ADI that was set using the 2-year dog feeding study with a NOEL of 40 ppm. The NOEL on the dog study was based on cholinesterase inhibition. A tenfold safety factor was used to arrive at an ADI of 0.10 mg/kg/day and an MPI of 6 mg/kg for a 60 kg human. However, according to current policy a safety factor of 10 should only be employed for cholinesterase inhibiting pesticides when there is an ". . . adequate spread between the NOEL for cholinesterase inhibition and the NOEL for any other significant effect observed." In the 2-year feeding study in rats, the NOEL for systemic effects was 40 ppm, identical to the NOEL for cholinesterase inhibition. The systemic effects observed were a slight decrement in body weight gain and moderate liver cell vacuolation in males. These are significant effects; therefore, in order to provide a sufficient safety factor for these effects, the original ADI was decreased by a factor of 5 in order to equate to the use of a hundredfold safety factor with the rat NOEL of 40 ppm.

Since the ADI is now set on a systemic effects for lifetime exposure with a safety factor of 100 rather than on cholinesterase inhibition, the tolerance expression under 40 CFR 180.261 will be amended by deleting the reference to "cholinesterase-inhibiting" residues.

The theoretical maximum residue contribution (TMRC) is the theoretically maximum amount of residues of a pesticide that might be present in the human diet, based on assumptions the Agency makes about the average human daily intake of foods containing residues at the level of the established tolerances. The TMRC to the human diet from existing tolerances for phosmet is 1.0932 mg/day (in a 1.5 kg diet). The TMRC is equivalent to 98.29% of the ADI employing the United States Department of Agriculture food factors. Since virtually all of the ADI has been used up by the TMRC and the Agency is aware of a potential oncogenic response to phosmet, new tolerances and/or new uses will not be approved if they contribute significantly to the TMRC and/or result in a significant increase in the dietary exposure.

Summary of Tolerances Issued for Phosmet

Commodity	Tolerances (ppm)			(MRL)
	United States[1]/	Canada[2]/	Mexico[3]/	International (Codex)
Alfalfa	40.0	0.1 (N)	--	20.0
Almonds, hulls	10.0	--	--	--
Apples	10.0	10.0	--	10.0
Apricots	5.0	--	--	5.0
Blueberries	10.0	5.0	--	10.0
Cattle, fat	0.2	0.1 (N)	--	1.0
Cattle, meat	0.2	0.1 (N)	--	1.0
Cattle, mby	0.2	0.1 (N)	--	1.0
Cherries	10.0	7.0	--	--
Citrus fruits	5.0	--	--	5.0
Corn, fresh (including sweet K + 6 WHR)	0.5	--	--	0.2
Corn, fodder	10.0	--	--	--
Corn, forage	10.0	--	--	--
Corn, grain	0.5	--	--	--
Cottonseed	0.1	--	--	--
Cranberries	10.0	--	--	--
Goats, fat	0.2	--	--	--
Goats, mbyp	0.2	--	--	--
Goat, meat	0.2	--	--	--
Grapes	10.0	10.0	--	--
Hogs, fat	0.2	0.1 (N)	--	--
Hogs, mbyp	0.2	0.1 (N)	--	--
Hogs, meat	0.2	0.1 (N)	--	--
Horses, fat	0.2	--	--	--
Horses, mbyp	0.2	--	--	--
Horses, meat	0.2	--	--	--
Kiwi fruit	25.0	1.0	--	15.0
Nectarines	5.0	--	--	5.0
Nuts	0.1 (N)	--	--	0.1
Peaches	10.0	10.0	--	10.0
Pears	10.0	10.0	--	10.0
Peas	0.5	--	--	0.1
Peas, forage	10.0	--	--	--
Peas, hay	10.0	--	--	--
Plums (fresh prunes)	5.0	5.0	--	--
Potatoes	0.1	0.1 (N)	--	0.5
Sheep, fat	0.2	--	--	--
Sheep, mbyp	0.2	--	--	--
Sheep, meat	0.2	--	--	--
Sweet potatoes	10.0	--	--	10.0
Tomatoes	2.0	--	--	--
Cottonseed oil	0.2	--	--	--

1/ The U.S., and Codex Maximum Residue Level (MRL) are expressed as residues of phosmet and its oxygen analog.

2/ Canadian tolerances are expressed in terms of residues of phosmet *per se*.

3/ There are no Mexican tolerances established for phosmet.

N - negligible; tolerances are set at the limit of detection.

3. REGULATORY POSITIONS AND RATIONALES

3.1 SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on phosmet the Agency has made the following determinations:

1. Special Review: None of the risk criteria listed in 40 CFR 154.7 have been exceeded for phosmet. Therefore, no referral to Special Review is being made at this time.

   Rationale (Humans): The data presently available for phosmet provide only limited evidence for oncogenicity in animals at this time. The two-year mouse study indicated phosmet produced an increased incidence of liver tumors only at the highest dose tested in males, and trends for liver tumors in females, in only one strain and species of mice and in only one experiment. In addition, phosmet was essentially non-mutagenic (in a limited and inadequate battery of tests) and no positive correlations with respect to oncogenicity and mutagenicity could be made with known structural analogues. After the two-year rat oncogenicity and additional mutagenicity studies are submitted and evaluated, the Agency will reassess the oncogenicity issue and determine if dietary and worker carcinogenicity risk assessments are necessary.

   Rationale (Non-Target Organisms): The available laboratory data indicates that phosmet is very highly toxic to fish. Terrestrial residue analysis and aquatic runoff modeling further indicate that certain use patterns of phosmet could result in exposure of certain aquatic organisms (including endangered species) to potentially hazardous levels of the pesticide. The Agency has not received any reports on fish kills associated with the use of phosmet during its use history. Additional data are needed before the Agency can complete a full assessment of this hazard potential. After the evaluation of required environmental fate data, chronic fish and aquatic invertebrate data, and residue field studies, the Agency will determine if it should initiate a public interim review process by placing the chemical in Special Review.

2. Tolerance Reassessment: The Agency will reassess the adequacy of the existing tolerances after required metabolism data and residue data have been submitted.

Rationale: Data gaps exist for plant and animal metabolism, storage stability, magnitude of the residues in several raw agricultural commodities and processed food and feed items. Upon receipt of the data required in Table A, the Agency's conclusions with regard to the adequacy of established tolerances are subject to change. Since the data required for individual commodities are dependent on the metabolism data, the metabolism data will be obtained and reviewed prior to any required residue data.

3. New Tolerances/New Uses: New tolerances and uses will be issued only on a case-by-case basis after considering the effects on the theoretical maximum residue concentrations (TMRC), the maximum permitted intake (MPI), and the oncogenic risks.

   Rationale: Available residue data, including processing data and metabolism data, are insufficient and/or lacking. This lack of data prohibits the Agency from conducting a full tolerance reassessment. The Agency is also concerned that virtually all of the ADI has been used up by the TMRC based upon existing tolerances. The data from the mouse oncogenicity results indicating oncogenic response has generated additional concerns. Therefore careful consideration will be given to the increase in dietary exposure before approving new tolerances/uses.

4. Tolerance expression: The tolerance expression for phosmet under 40 CFR 180.261 will be amended by deleting the reference to "cholinesterase inhibiting" residues.

   Rationale: The ADI is now set on systemic effects for lifetime exposure rather than on cholinesterase inhibition.

5. Endangered Species Concerns: The Agency has determined that endangered species label restrictions are necessary precaution during the time that environmental data required by this Standard is generated and analyzed. The Agency is requiring endangered species labeling for all end-use products intended for use on apples, pears, alfalfa, corn, and cotton to protect certain threatened aquatic species, and for all end-use protects intended for terrestrial food crop use in certain counties in California to protect the elderberry longhorn beetle and the Delta green ground beetle. Labeling statements will require users to obtain and review a bulletin on use in areas where these aquatic species and insects are found and in those areas not to use phosmet. The Agency intends to formally consult with the Office of Endangered Species (OES), U.S. Department of Interior (USDI), and request a biological opinion on the potential of phosmet use to jeopardize endangered species. To further evaluate the hazard to aquatic organisms, including endangered species, the Agency is requiring aquatic field monitoring

data to assess the levels of phosmet entering the aquatic ecosystems from phosmet use on apple orchards, corn, cotton, and alfalfa crops. (Refer to Section 3.4 for labeling requirements)

Rationale: The required labeling restrictions are based upon the high toxicity of phosmet to aquatic organisms and the potential toxicity to these endangered species from specific terrestrial crop applications with a potential for aquatic contamination. Based upon maximum use rates of phosmet on apple orchards, corn, cotton and alfalfa fields, the Agency estimated the environmental concentration of phosmet in water from spray drift and runoff, to equal or exceed the LC_{50} for certain aquatic species. This indicates that phosmet use may affect endangered species; therefore endangered species labeling are required.

6. Restricted Use (Aquatic): The Agency will not restrict certain uses of phosmet to certified applicators at this time but has determined that precautionary labeling for aquatic organisms is required. (Refer to Section 3.4 for labeling requirements).

   Rationale: The required labeling restrictions are based on the high toxicity of phosmet to aquatic organisms. Available data indicate that phosmet is highly toxic to fish and aquatic invertebrates (including freshwater and estuarine organisms). Analysis of terrestrial residue and aquatic runoff modeling (theoretical calculation) indicate that certain use patterns of phosmet could results in a hazard to aquatic organisms; however, the Agency has not received any reports on fish kills following phosmet application during its long use history. Fish, invertebrate, estuarine/marine organisms and field monitoring data, plus environmental fate data are required to complete the hazard assessment for aquatic organisms. Should additional data demonstrate that phosmet poses risks to aquatic organisms that could be mitigated by increased controls in application, restricted use classification may be required.

7. Reentry Requirements: The Agency is imposing an interim 24-hour reentry interval. (Refer to section 3.4 for labeling requirements.)

   Rationale: Reentry data are required by 40 CFR 158.140 for pesticides which have use patterns likely to result in high dermal and/or inhalation exposure to persons entering pesticide treated fields. Phosmet is registered for agricultural uses that could involve substantial prolonged human exposure to the residues on foliage. There are not sufficient data available for the Agency to determine the extent of protection necessary to minimize exposure to farmworkers and others who enter fields subsequent to phosmet application. The crops for which foliar dissipation data are required are those whose propagation requires human tasks that involve substantial, prolonged dermal contact with pesticide treated surfaces following foliar application of phosmet. Data to address this concern are lacking and have been requested under the February 28, 1985, Reentry Data Call-In Notice for phosmet. This data is due by December 1986. Until the required data are submitted and evaluated, an interim 24-hour reentry interval is being required to lessen exposure to workers entering treated fields. End-use products with directions for use on such crops must include the label statements required under PR Notices 83-2 and 84-1. A 24-hour reentry interval must be included in the required written or oral warnings given to farmworkers.

8. Protective Clothing Requirement: The Agency has determined that protective clothing be worn by mixer/loaders and applicators. Product labels will be required to specify that mixer/loaders wear mid-forearm to elbow length chemical resistant gloves, a long sleeve shirt, and long pants. Labels will require applicators to wear a long sleeve shirt and long pants and a wide-brimmed chemical resistant hat during upward directed foliar spraying to fruit and nut crops. The Agency will also require that a special glove permeability study be conducted. (Refer to Section 3.4 for labeling requirements.)

   Rationale: Phosmet is a typical organophosphate chemical that can induce cholinesterase inhibition upon repeated significant exposure. Protective clothing is necessary to lessen exposure to workers and to protect against acute toxicity and potential oncogenic risk during mixing, loading and application of phosmet. The glove permeability study will permit the Agency to evaluate dermal exposure and risks with protective clothing.

9. Adverse Reactions In Pets: The Agency will analyze the safety and efficacy data of a phosmet flea dip formulation (Paramite) to determine if further regulatory action is warranted. A warning statement indicating that improper dilution of the product could cause serious injury to pets is also being required during the interim. (Refer to Section 3.4 for labeling requirements).

   Rationale: Complaints of animal poisoning incidents have been received relating to the use of phosmet. It has been alleged that phosmet causes illness and death in dogs and cats. It is uncertain if these incidents were due to misuse, animal stress (heat, exercise), or age or type of dog and cat treated. As with other organophosphates, phosmet can inhibit plasma and erythrocyte cholinesterase activity in animals. Since there is a history of complaints and reactions associated with the use of this product on animals, existing data submitted in support of this product's use on pets will be analyzed to determine if the minimum effective rate is being recommended and if it demonstrates an adequate safety margin to animals over its use level. If the data do not demonstrate an adequate margin of safety to animals when used as directed, further regulatory actions may be warranted, including labeling direction changes, use restrictions or cancellation.

10. Cranberries: The Agency has determined that the tolerance for cranberries should be revoked because there are no registered uses for phosmet on cranberries. The Agency cannot evaluate the adequacy of the tolerance on unspecified directions for use.

    Rationale: A tolerance of 10 ppm was established for combined residues of phosmet and its oxygen analog in or on cranberries based upon use directions proposed in 1974. Currently there are no registered uses for phosmet on cranberries.

11. Processing data: The Agency is requiring processing data for the following raw agricultural commodities: potatoes, apples, plums, peaches, grapes, field corn grain, and cottonseed.

    Rationale: There are no data and/or insufficient data to determine whether residues of phosmet concentrate when these commodities are processed into food or feed items.*

12. Rotational Crop Label Restrictions: The Agency is not requiring a rotational crop restriction. If required data demonstrate that follow-up crops take up phosmet residues from soil, rotational crop restrictions or tolerances in those unregistered crops may be necessary.

    Rationale: The Agency lacks appropriate rotational crop data at the present time to determine whether planting food or feed crops in phosmet-treated soils would result in illegal residues in these crops. Several factors lead the Agency to believe that rotational crop restrictions are not necessary to prevent illegal residues: (1) Preliminary data indicates that the half-life of phosmet is < 11 days. Degradation in soil is primarily through hydrolysis. Soil microorganisms and photodegradation accelerates the process. Potatoes receive the highest application rate of phosmet near the time of harvest. Since the tolerance for phosmet is at or near the level of detection, this fact suggests that plant uptake may be negligible.

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*The Delaney Clause in section 409 of the Federal Food, Drug and Cosmetic Act bars the establishment of food active regulations for substances which induce cancer in man or test animals. Phosmet has been found to produce an oncogenic response in test animals. The Agency will be soliciting comments on Delaney Clause issues regarding pesticides which have produced positive oncogenic responses in chronic animal studies. This notice is scheduled for issuance before the end of 1986.

13. Groundwater Concerns: The Agency is not imposing a groundwater advisory statement on phosmet labeling at this time.

Rationale: The Agency issued a groundwater Data Call-In (DCI) notice on June 29, 1984. The registrant cited five studies in response to the DCI. None of the studies satisfied the data requirements. Since they were not conducted in accordance with current testing guidelines, additional data must be submitted to the Agency to satisfy these requirements. To date, the Agency is not aware of incidents where phosmet has contaminated groundwater. After review of the requested data, the Agency will take appropriate steps to protect groundwater if necessary.

14. Continuation of Registration: While data gaps are being filled, currently registered end-use products containing phosmet as the sole active ingredient may be sold, distributed and used, subject to terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or inadequate (see FIFRA section 3(c)(2)(B) and section 3(c)(7)), unless available data indicate that use of the product is likely to cause unreasonable adverse effects on the environment.

Issuance of this Standard provides a mechanism for identifying data needs. After receipt and review of the data the Agency will determine if additional regulatory changes are necessary.

3.2 CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain phosmet as the sole active ingredient, (solvents or diluents should be declared as inert) bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

3.3 ACCEPTABLE RANGES AND LIMITS

3.3.1 PRODUCT COMPOSITION STANDARD

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain phosmet as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

3.3.2 ACUTE TOXICITY LIMITS

The Agency will consider registration of technical grade and MPs containing phosmet provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3.3.3 USE PATTERNS

To be registered under this Standard, MPs may be labeled for formulation into end-use products (EPs) only for the commodities listed below.

TERRESTRIAL FOOD CROP
(Agricultural Crops)

Alfalfa
Almond
Apple
Apricot
Blueberry
Cherry, Sour (Tart)
Citrus Fruits
Corn
Cotton
Grapes
Kiwi Fruit
Lemon
Nectarines
Orange
Peach
Pear
Peas
Pecan
Plum
Potato
Prune

TERRESTRIAL NON-FOOD CROPS
(Ornamental Plants)
Christmas Tree Plantations
Loblolly Pine (seedlings)
Ornamental Shrubs
Ornamental and/or Shade Trees
Slash Pine (seedlings)
Western Pines
White Pines (seedlings)
(Non-Crop, Wide Area, and General Indoor/Outdoor Treatments)
Wide Area and General Outdoor Treatments
Limited to Fire Ant Control

DOMESTIC OUTDOOR
(Ornamental Plants)
Domestic Dwellings, Outdoor

INDOOR
(Agricultural Crops)
Sweet potato
(Pets and Domestic Animals)
(Animals and Their Man-Made Premises)
Beef Cattle
Dogs/Cats
Swine

The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

3.4 REQUIRED LABELING

All MPs (and EPs if covered by Standard) must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II and the section below contains information on label requirements.

No product containing phosmet as a ingredient may be released for shipment by the registrant after one year of receipt of this Standard unless the product bears an amended label which complies with the requirements of this Standard.

No product containing phosmet as an active ingredient may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after twenty four months from issuance of the Standard unless the product bears an amended label which complies with the requirements of this Standard.

The following information must appear on the labeling:

3.4.1. Ingredients Statement

The ingredient statement for MPs must list the active ingredient as:

N-(Mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)

3.4.2. Use Pattern Statements

All MPs must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section 3.3.3. However, no use may be included on the label where the registrant fails to comply with the data requirements in Table A for that use pattern.

3.4.3 Precautionary Statements

Manufacturing Use Products (MP)

1. Labels for MPs must bear the following statements under the heading "Environmental Hazards."

   This pesticide is extremely toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

2. All MPs must bear the following protective clothing statement.

   When mixing/loading or otherwise handling the concentrate, wear mid forearm to elbow length chemical resistant gloves, long sleeve shirt, and long pants.

3. The directions for use must include the following statement:

   Formulators using this product are responsible for EPA registrations for their formulated product(s).

End-Use Products (EP)

1. All EPs for terrestrial food and non-food use and domestic outdoor uses must bear the following statements under the heading "Environmental Hazards";

This pesticide is extremely toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops while bees are actively visiting the treatment areas.

2. All EPs intended for use on apples, pears, alfalfa, corn, cotton and for terrestrial food uses in California must bear the following endangered species labeling:

   The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of federal laws. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

   Before using this pesticide in the following counties you must obtain the EPA Cropland Endangered Species Bulletin. The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildife Agency Headquarters or the appropriate Regional Office of either the U.S. Fish and Wildlife Service (FWS) or the U.S. Environmental Protection Agency. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

STATE (Regional office FWS) Species	COUNTY	
ALABAMA (Atlanta, GA.)	LAUDERDALE	MADISON
Slackwater darter	LIMESTONE	
Alabama cavefish	LAUDERDALE	
Freshwater mussels	COLBERT	MARSHALL
	JACKSON	MORGAN
ARIZONA (Albuquerque, N.M.)		
Woundfin	MOHAVE	
Gila topminnow	GRAHAM	SANTA CRUZ
ARKANSAS (Atlanta, GA.)	CLAY	RANDOLPH
Freshwater mussels	CLARK	SHARP
	CROSS	ST. FRANCIS
	LAWRENCE	
Leopard darter	SEVIER	
CALIFORNIA (Portland, OR.)		
Lahontan cutthroat trout	ALPINE	MONO
	NEVADA	PLACER
	SIERRA	
Unarmored threespine stickleback	LOS ANGELES	SANTA BARBARA
COLORADO (Denver, CO.)	BLANCO	MOFFAT
Colorado squawfish	DELTA	RIO
	GARFIELD	ROUTT
	MESA	
KENTUCKY (Atlanta, GA.)	BALLARD	McCRACKEN
Freshwater mussels	EDMUNDSON	PULASKI
	JACKSON	ROCKCASTLE
	LAUREL	WARREN
	MARSHALL	WAYNE
MISSISSIPPI (Atlanta, GA.)		
Bayou darter	COPIA	
NEVADA		
Moapa dace	CLARK	
Woundfin	CLARK	
Pahranagat	LINCOLN	
Cui-ui	WASHOE	
Pahrump killifish	CLARK	WHITE PINE

STATE(Regional office FWS) Species	COUNTY	
NEW MEXICO (Albuquerque, N.M.)	CHAVES	
Pecos gambusia	EDDY	
OHIO (Twin Cities, MN.)	CHAMPAGNE	MADISON
Scioto madtom	FRANKLIN	PICKAWAY
	LOGAN	UNION
OKLAHOMA (Albuquerque, N.M.)	LEFLORE	
Leopard darter	McCURTAIN	
TENNESSEE (Atlanta, GA.)	LAWRENCE	
Slackwater darter	WAYNE	
Freshwater mussels	BLOUNT	MARSHALL
	CLAIBORNE	MAURY
	DECATUR	RHEA
	FRANKLIN	ROANE
	HANCOCK	SCOTT
	HARDIN	SEQUATCHIE
	LINCOLN	SMITH
	LOUDON	SULLIVAN
TEXAS (Albuquerque, N.M.)		
Commanche Springs pupfish	JEFF DAVIS	
	REEVES	
Pecos gambusia	JEFF DAVIS	REEVES
	PECOS	
San Marcos gambusia	HAYS	
Houston Toad	BASTROP	BURLESON
Fountain darter	HAYS	
UTAH (Denver, CO.)		
Woundfin	WASHINGTON	
Colorado squawfish	CARBON	KANE
	DUCHESNE	SAN JUAN
	EMERY	UINTAH
	GARFIELD	WAYNE
	GRAND	
VIRGINIA (Newton Corners, MA.)		
Freshwater mussels	LEE	TAZEWELL
	RUSSELL	WASHINGTON
	SCOTT	WISE
	SMYTH	
CALIFORNIA (Portland, OR)		
Valley elderberry longhorn beetle	SACRAMENTO	MERCED
Delta green ground beetle	SOLANO	

3. The following worker reentry statement must be added to the labeling for products with directions for use on crops whose culture requires hand labor:

   Do not allow worker reentry into treated fields within 24 hours of application unless appropriate protective clothing is worn. Protective clothing means, at least, a hat or other suitable head covering, a long sleeved shirt and long legged trouses or a coverall type garment (all closely woven fabric covering the body, including the arms and legs) shoes and socks.

4. Products with directions for use on terrestrial food and non-food crops and domestic outdoor uses must bear the following protective clothing statement:

   When mixing/loading wear mid forearm to elbow length chemical resistant gloves, long sleeve shirt, and long pants. During the application wear long sleeve shirt and long pants. Applicator must also wear a wide-brimmed chemical resistant hat while spraying up toward fruit and nut crops.

   Any article of clothing worn while applying product must be cleaned before re-using. Clothing should be laundered separately from household articles. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be disposed of in a sanitary landfill, incinerated, or burned if allowed by state and local authorities.

5. Products with directions for use as livestock sprays, livestock dips, and dog and cat dips, must bear the following protective clothing statement:

   Applicators must wear long sleeved shirt, long pants, elbow length waterproof gloves, waterproof apron, and unlined waterproof boots.

6. Products with directions for use as a dog or cat dip must bear the following precautions:

   Improper dilution of this product could cause serious injury to your dog and/or cat.

4. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in section 1.1 are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end-use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

4.1 MANUFACTURING-USE PRODUCTS

A. Manufacturing-use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in sections 3.3 and 3.4 if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[1].

3. The labeling requirements specified for manufacturing use products in sections 3.3 and 3.4.

4. Administrative requirements (application forms, Confidential Statements of Formula, data compensation provisions) associated with reregistration.

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[1] Data requirements are listed in the three Tables in Appendix 1 of this Registration Standard. The Guide to the Tables in that appendix explains how to read the tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard.

Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption of that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

Manufacturing-use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

4.2 END-USE PRODUCTS

End-use products containing this pesticide as the sole active ingredient* are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in sections 3.3 and 3.4 if they pertain to the end-use product.

2. If eligible for the formulator's exemption[2], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end-use products in section 3.4.

* solvents or diluents must be declared as inerts. The Agency does not have data indicating that these solvents are insecticidal.

End-use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

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[2] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing-use product you purchase (Table B).

Two circumstances nullify this exemption:

(1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you lose the exemption and become subject to the data requirements in Table A.

(2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to those data requirements. EPA will inform you if this occurs.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.

5. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA section 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[3]

5.1 WHAT ARE GENERIC DATA?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

5.2 WHO MUST SUBMIT GENERIC DATA?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA section 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA section 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA section 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA section 6(e)).

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[3] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

5.3 WHAT GENERIC DATA MUST BE SUBMITTED?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

5.4 HOW TO COMPLY WITH DCI REQUIREMENTS

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

(a) File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

(b) Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA section 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

5.5 PROCEDURES FOR REQUESTING A CHANGE IN TESTING PROTOCOL.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

5.6 PROCEDURES FOR REQUESTING EXTENSIONS OF TIME

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

5.7 EXISTING STOCKS PROVISION UPON SUSPENSION OR CANCELLATION.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA section 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

6. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing-use product, these data are listed in Table B. If you have an end-use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end-use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. (See sections 5.4, 5.5, 5.6, and 5.7.) You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options 1 (submit data) or 6 (cancellation of registration), listed under section 5.4.

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

7. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in section 3.4 of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in section 3.4, EPA may issue a "Notice of Intent to Cancel" the registration of your product under FIFRA section 6(b)(1).

8. INSTRUCTIONS FOR SUBMISSION

8.1 MANUFACTURING-USE PRODUCTS

For manufacturing products (MUPs) containing phosmet as the sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

   a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[4]

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Formulator's Exemption Statement (EPA Form).

   d. Evidence of compliance with data compensation requirements of FIFRA section 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

   d. Product Specific Data Report (EPA Form 8580-4).

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[4] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

For manufacturing-use products containing phosmet in combination with other active ingredients(other than solvents)*.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA section 3(c)(2)(B) Summary Sheet, with appropriate attachments[4] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

8.2 For end-use products containing phosmet as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[4] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form   ), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

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* Solvents or diluents such as petroleum distillates must be declared as inerts.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End-use product labeling must comply specifically with the instructions in Section 3 (Regulatory Position and Rationale).

8.3 INTRASTATE PRODUCTS

Intrastate products containing phosmet either as the sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

8.4 ADDRESSES

The required information must be submitted to the following address:

George T. LaRocca
Product Manager 15
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing-use product.

Table C contains product-specific data requirements that apply only to an end-use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data submission[1]
§158.120 Product Chemistry						
Product Identity and Composition:						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	A,B,H,I	Partially	— 2/	Yes 3/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	A,B,H,I	No	—	Yes 4/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	A,B,H,I	No	—	Yes 5/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	A,B,H,I	No	—	Yes 6/	12 Months
62-2 - Certification of Ingredient Limits	TGAI	A,B,H,I	No	—	Yes 7/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	A,B,H,I	Partially	00112317, 00112263 00126567, 00112314	Yes 8/	12 Months
Physical and Chemical Characteristics 9/						
63-2 - Color	TGAI	A,B,H,I	No	—	Yes	6 Months
63-3 - Physical State	TGAI	A,B,H,I	No	—	Yes	6 Months
63-4 - Odor	TGAI	A,B,H,I	No	—	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data Submission[1]
§158.120 Product Chemistry (continued)						
Physical and Chemical Composition (continued)						
63-5 - Melting Point	TGAI	A,B,H,I	No	--	Yes	6 Months
63-6 - Boiling Point	TGAI	A,B,H,I	No 10/	--	No 10/	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	A,B,H,I	No	--	Yes	6 Months
63-8 - Solubility	TGAI or PAI	A,B,H,I	No	--	Yes 11/	6 Months
63-9 - Vapor Pressure	TGAI or PAI	A,B,H,I	No 12/	--	No 12/	
63-10 - Dissociation Constant	TGAI or PAI	A,B,H,I	No	--	Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	A,B,H,I	Yes	00148325	No 11/	
63-12 - pH	TGAI	A,B,H,I	No	--	Yes	6 Months
63-13 - Stability	TGAI	A,B,H,I	No	--	Yes	6 Months
Other Requirement:						
64-1 - Submittal of Samples	TGAI or PAI	A,B,H,I	No	--	Reserved 13/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

FOOTNOTES FOR PREVIOUS PAGES

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§158.120 Product Chemistry

1/ Due dates refer to number of months following receipt of this Registration Standard or as otherwise indicated.

2/ Information is obtained from the product registration file for the 94% technical product.

3/ The following information on the 90% technical (476-2178) is required: the product name, trade name (if different), and any experimental or internal code number the company has assigned.

4/ The following information is required: (a) details of the manufacturing process, including the relative amounts of beginning materials; a description of the equipment used to produce the product; reaction conditions; the duration of each step of the process; purification procedures; and quality control measures for the 90% and 94% technical products; (b) the name and address of the manufacturer, producer or supplier of each beginning material used to manufacture the 90% technical. A copy of all technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier describes the composition and properties of each beginning material used to manufacture the 90% technical must also be submitted; (c) the address of the manufacturer, producer, or supplier of each beginning material used to manufacture the 94% technical.

5/ A discussion of each impurity which may be present at $\geq$ 0.1% based on knowledge of the beginning materials, all possible chemical reactions, and any contamination is required for the 90% and 94% technical products.

6/ Five or more representative samples of the 90% and 94% technical products must be analyzed for the amount of active ingredient and each impurity present at $\geq$ 0.1% (w/w) using valid analytical methods.

7/ The following data are required for the 90% and 94% technical products: (a) upper and lower limits must be provided, validated, and certified; (b) upper limits must be provided, validated and certified for each toxicologically significant impurity present at <0.1% (w/w); (c) upper limits must be provided, validated and certified for each impurity present at $\geq$ 0.1% (w/w).

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

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§158.120 Product Chemistry (footnotes continued)

8/ Quantitative methods to determine the phosmet and all toxicologically significant impurities for which a certified limit must be submitted on the 90% and 94% technical products. Each method must be accompanied by validation studies of the precision and accuracy of the method.

9/ Adequate physical/chemical property information for the 90% and 94% technical products must be submitted unless otherwise indicated.

10/ Not required because the technical is a solid at room temperature.

11/ Data was required by the June 29, 1984 Data Call-In letter for groundwater data.

12/ Not required because the melting point of the pure form of the active ingredient is > 30 °C.

13/ If samples are needed the Agency will request them.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry					
171-4 - Nature of Residue (Metabolism) 2/					
- Plants	PAIRA	Partially	00037167, 00112312,	Yes 3/	18 Months 4/
- Livestock	PAIRA	Partially	001122241	Yes 5/	18 Months 4/
171-4 - Residue Analytical Method 2/					
- Plant Residue	TGAI and Metabolites	Yes	00037165, 00037166, 00037168, 00056849, 00056852, 00056862, 00067069, 00078567, 00084808, 00087762, 00095485, 00112241, 00112262, 00112265, 00112274, 00112296, 00112313, 05004211	No 6/	
- Animal Residues	TGAI and Metabolites	Yes	00112241	No 6/	
- Storage Stability Data	TGAI and Metabolites	Partially	00056850, 00056851, 00084815, 00097846, 00112279	Yes 7/	15 Months
171-4 - Magnitude of Residue - Residue Studies for Each Food Use 2/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission[1]
§158.125 Residue Chemistry (continued)					
171-4 - Magnitude of the Residue (continued) 2/					
- Root and Tuber Vegetable Group 8/					
Potatoes	TEP	Partially	00094636, 00112260 00112271, 00116855	Yes 9/	18 Months 4/
Sweet Potatoes	TEP	Partially	00112262	Yes 10/	18 Months 4/
- Legume Vegetable (Succulent or Dried) Group 11/					
Peas (Dry and Succulent)	TEP	Partially	00084814	Yes 12/	18 Months 5/
- Foliage of the Legume Vegetables Group 13/					
Pea Vines and Hay	TEP	Partially	00061721, 00084814, 00112283	Yes 12/	18 Months 4/
- Fruiting Vegetables Group 14/					
Tomatoes	TEP	Yes	00081616	No 15/	
- Citrus Fruits Group 16/					
Grapefruit	TEP	Partially	00084810, 00112283	Yes 17/	18 Months 4/
Lemons	TEP	Partially	00084810, 00112283	Yes 17/	18 Months 4/
Oranges	TEP	Partially	00084810, 00112283	Yes 17/	18 Months 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.125 Residue Chemistry (continued)					
- Pome Fruit Group 18/					
Apples	TEP	Partially	00044198, 00056854, 00056858, 00093486, 00106602, 00112302	Yes 19/	18 Months 4/
Pears	TEP	Yes	00093486, 00116602	No	
- Stone Fruits Group 20/					
Apricots	TEP	Partially	00037173	Yes 21/	18 Months 4/
Cherries	TEP	Yes	00037174	No 22/	
Nectarines	TEP	Partially	00037173, 00093486	Yes 23/	18 Months 4/
Peaches	TEP	Yes	00037173, 00056854, 00093486, 00106602	Yes 24/	18 Months 4/
Plums (fresh prunes)	TEP	Partially	00037174, 00093486	Yes 25/	18 Months 4/
- Small Fruits and Berries Group 26/					
Blueberries	TEP	Yes	00084809	No	
Cranberries	TEP	Yes	00084812, 00112283	No 27/	
Grapes	TEP	Yes	00037175, 00112247	Yes 28/	18 Months 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.125 Residue Chemistry (continued)					
- Tree Nuts Group 29/					
Almonds	TEP	Partially	00044198, 00056854, 00056858, 00093486,	Yes 30/	18 Months 4/
Pecans	TEP	Partially	00084813	Yes 30/	18 Months 4/
- Cereal Grains Group 31/					
Corn, Field and Fresh (including sweet kernels) plus cob with husks removed)	TEP	Yes	00084811, 00112283	Yes 32/	18 Months 4/
- Forage, Fodder, Hay, and Straw of Cereal Grains Group 33/					
Corn Forage and Fodder	TEP	Yes	00037157, 0084811	No	
- Non-grass Animal Feeds Group 34/					
Alfalfa	TEP	Yes	00056858, 00095485	No 35/	
- Miscellaneous Commodities					
Cottonseed	TEP	Partially	00067068, 00112245, 00112281	Yes 36/	18 Months 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.125 Residue Chemistry (continued)					
Kiwifruit	TEP	Yes	00112279	No	
- Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	TGAI or Plant Metabolites	Partially	00037155, 00037161, 00037162, 00056860, 00078568, 00078570, 00112249, 00112310, 00112316, 00112325, 05012698	Reserved 37/	

1/ Due dates refers to number of months following receipt of this Registration Standard or as otherwise indicated.

2/ Since completion of these data requirements requires a tiered approach (metabolism -> residue analytical methods -> crop field trials/storage stability/processed foods and feeds -> meat/milk/poultry/eggs), the registrants must submit any proposed variations in the timeframe schedule for data submissions within 90 days after receipt of this Guidance Document. Allowances to the required time lines will be made only if sufficient justification is provided, i.e., the registrant states he does not have this data and due to the seasonal nature of the crop and the tiered approach requirement, additional time is needed to satisfy the data requirement. The Agency reserves the right to request necessary studies earlier than the period specified in the above tables and/or proposed timeframes.

3/ Data must be submitted on the uptake, distribution, and metabolism of ^{14}C-carbonyl or ring-labeled phosmet in representative mature crops, preferably an orchard tree fruit, potatoes, and corn (grain and forage) following foliar applications. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry. Data must also be presented that reflect the extraction efficiency of the solvent(s) used to remove residues following application of phosmet to living plants.

Note: Representative samples from the above-described tests must also be analyzed by accepted enforcement methods to ascertain that these methods are capable of determining all metabolites of concern.

4/ Progress reports on the nature of the residue and crop field trial data is required 9 months after receipt of this Registration Notice. See footnote 3.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

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§158.125 Residue Chemistry (footnotes continued)

5/ Metabolism studies utilizing ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with ^{14}C-ring- or carbonyl-labeled phosmet at a concentration in the total diet that will result in sufficient residues in the tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dosing. Milk and eggs must be collected twice daily. ^{14}C-Residues in muscle, fat, kidney, liver, milk, and eggs must be characterized.

Beef cattle and swine must be dermally dosed with ^{14}C-ring- or carbonyl-labeled phosmet at a concentration that will result in sufficient residues in the tissues for characterization. Animals must be sacrificed 24 hours (beef cattle and swine) and 3 days (beef cattle only) after treatment and residues characterized in muscle, fat, kidney, and liver.

Note: Representative samples from the metabolism studies requested above must also be analyzed using accepted enforcement methods to ascertain their validity.

6/ If the requested data regarding the nature of the residue in plants and animals reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

7/ The storage intervals and conditions of samples used to support all established tolerances for residues must be submitted. These data must be accompanied by data depicting the percent decline in residues at the times and under the conditions specified. (No additional stability studies are required for plant commodities stored frozen for up to 1 year). On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified, with the exception of plant commodities stored frozen for $\leq$ 1 year.

Data should delineate the stability of phosmet and its oxygen analog in animal products (tissues, milk, and eggs). Spiked samples should be stored at subfreezing temperatures for intervals approximating the storage intervals associated with treated samples used to determine the magnitude of the residue.

It should be noted that the nature of the residue in plants and animals has not been adequately described. If the requested metabolism data indicate the presence of additional residues of toxicological concern in plant or animal commodities, data depicting the stability of such residues in storage will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

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§158.125 Residue Chemistry (footnotes continued)

8/ A group tolerance is not appropriate at the present time for the following reasons: (a) additional data are required to support the established tolerance for residues in or on potatoes; (b) residue data and proposed uses are required for additional members of this group (carrots, radishes, and sugar beets); (c) the use on sweet potatoes (postharvest) is significantly different than that on potatoes (foliar) and the tolerance for residues in or on sweet potatoes (10 ppm) is more than 5X greater than that for residues in or on potatoes (0.1 ppm). The tolerance for residues in or on sweet potatoes is too low and must be revised on receipt of required data. Thus, if a crop group tolerance is sought to cover foliar uses on members of this crop group, sweet potatoes must specifically be excluded.

9/ Residue data in or on potatoes, reflecting the maximum number of foliar applications and harvested 7 days after the last foliar application with a WP formulation at 1 lb ai/A, must be submitted. Applications must be made with ground, aerial, and ULV equipment, in separate tests. Tests must be conducted in ID, ME, OR, WA, and WI, which represent the major U.S. potato production regions. The registrant must propose a maximum number of applications or the maximum seasonal use rate and submit data supporting such use.

Data reflecting residues in granules, chips, and dried potatoes processed from potatoes bearing measurable weathered residues must be submitted. Exaggerated rates of application may be necessary to achieve such residue levels. If residues are found to concentrate in any of the processed commodities, appropriate food/feed additive tolerances must be proposed.

10/ Data depicting residues in or on unwashed sweet potatoes treated postharvest with the 5% D at 0.2 oz ai/50 lb must be submitted. Samples must be collected immediately after treatment and at regular (weekly) intervals thereafter until residues begin to decline. An appropriate tolerance revision must be proposed.

11/ A group tolerance is inappropriate at the present time for the following reasons: (a) proposed use directions and residue data for one succulent and one dried variety of beans, and soybeans, all of which are representative crops of the "Legume Vegetables Group" must be submitted. (b) additional data are required reflecting residues in or on peas (succulent and dried) reflecting the maximum number of foliar applications of phosmet.

12/ The registrant must propose a maximum number of seasonal applications of phosmet and appropriate data supporting such use must be submitted. Data reflecting the maximum number of applications must be submitted using the 50% WP at 1 lb/A using 20 to 50 gal water/A by ground and 5 to 10 gal water/A by aerial equipment. Pea samples (peas, pods, dry seeds and forage) must be collected 7 days after the last application, and hay samples must be collected 10 days after the last application. Tests must be conducted in WA and OR, the major U.S. pea production areas in the Pacific Northwest (Agricultural Statistics, 1984, p. 163).

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

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§158.125 Residue Chemistry (footnotes continued)

13/ A group tolerance is not appropriate at the present time for the following reasons: (a) proposed use directions must be submitted along with appropriate data for vines and hay of beans, and for forage, hay and straw of soybeans; (b) additional data are required reflecting residues in or on peas vines and hay.

14/ A group tolerance is not appropriate at the present time because a proposal for use and residue data in support of such use are required for peppers, a representative commodity of the "Fruiting Vegetables Group".

15/ Phosmet is not registered in the U.S. for use on tomatoes. Available residue data support the established tolerance for residues of phosmet in or on phosmet-treated tomatoes grown in Mexico. Since tomatoes imported into the U.S. from Mexico are sold exclusively on the fresh market, no data regarding the potential for concentration of residues on processing are required. However, it should be noted that if registration of phosmet for use on U.S. grown tomatoes is requested in the future or imported tomatoes are marketed other than for fresh market use only, additional residue data will be required.

16/ The data do not fully support the established group tolerance for phosmet residues in or on citrus for the following reasons (a) tests with grapefruit did not include the maximum number of applications/seasons or the use of spray oil, and (b) tests with lemons did not include the use of multiple applications at the maximum application rate. In addition, the data indicate that residues may concentrate up to 4x upon processing to citrus oil.

17/ Residue data concerning grapefruit and lemons treated with 3 foliar applications made 30 days apart with the 50% WP formulation at 0.5 lb ai/3000 gal/A (15 lb ai/A) tank mixed with a suitable spray oil must be submitted. A 7-day preharvest interval must be observed. Applications must be made using ground equipment only. Tests must be conducted in CA (both crops) and AZ (lemons only) which represent the major production areas in which use is permitted (Agricultural Statistics, 1974, p. 200).

A food additive tolerance at 4X the accepted tolerance for residues in or on the raw agricultural commodity must be proposed for residues in citrus oil.

18/ Based on the available data for apples and pears, representative commodities for the pome fruits group, the registrant may propose a 10 ppm tolerance for residues of phosmet and it O-analog in or on the crop group "Pome Fruit". See footnote 20.

19/ Data reflecting phosmet residues in or on apple products (dry pomace and juice) processed from whole apples bearing measurable weathered residues must be submitted. If residues are found to concentrate in any of the processed commodities, appropriate food/feed additive tolerances must be proposed. Also, to obtain a more acceptable estimate of dietary exposure, the Agency is requiring additional processing studies indicating the effects of washing and cooking.

TABLE A

GENERIC DATA REQUIREMENTS FOR PHOSMET

Residue Chemistry (footnotes continued) .

20/ A crop group tolerance is not appropriate because additional data are required to support the established tolerance for residues in or on plums.

21/ Submit residue data reflecting the maximum number of applications in or on apricots 14 days after the last foliar application with a WP formulation at 0.75 lb ai/100 (3 lb ai/A). Tests must be conducted using ground equipment. Tests must be conducted in CA which products 95.7 percent of the total commercial U.S. apricot crop (Agricultural Statistics, 1984, p. 193). As an alternative to submission of these data, the registrant may satisfy the data requirement for plums and propose a crop group tolerance for residues in or on members of the stone fruits group.

22/ No additional residue data are required, however the tolerance entry (40 CFR §180.261) will be amended to read "cherries sour" rather than cherries.

23/ Data reflecting residues of concern and the maximum number of applications in or on nectarines following the last foliar application with a WP formulation at 0.75 lb ai/100 gal (3 lb ai/A) must be submitted. Tests must be conducted using ground equipment. Tests must be conducted in CA which represents virtually all of U.S. nectarine production (Agricultural Statistics, 1984, p. 213, which presents nectarine production data for CA only). As an alternative to submission of these data, the registrant may submit the requested data for plums and propose a group tolerance for residues in or on members of the stone fruits group.

24/ Although sufficent data are available to ascertain the adequacy of the established tolerances, the Agency is requiring processing studies (washing and cooking) to obtain a more accurate estimate of dietary exposure.

25/ Data must be submitted reflecting residues of concern and the maximum number of applications in or on plums and fresh prunes following the last foliar application with a WP formulation at 0.75 lb ai/100 gal (3 lb ai/A). Tests must be conducted using ground equipment. Samples must be collected 7 days after the last treatment. Tests must be conducted in CA which represents 91 percent of the total U.S. plum and fresh prune production (1982 Census of Agriculture, Vol. 1, Part 51, p. 365).

Fresh prunes bearing measurable weathered residues must be processed to dried prunes to determine if concentration of residues occurs; if so, a food additive tolerance must be proposed.

26/ A group tolerance is inappropriate at the present time for the following reason: proposed use directions must be submitted along with appropriate supporting data for additional crop group members strawberries and a *Rubus* spp.

§158.125 Residue Chemistry (footnotes continued)

27/ Although a tolerance on cranberries was previously based upon a specific use pattern there are currently no registered uses for phosmet on cranberries. Therefore the Agency will propose revocation of this tolerance under the Tolerance Revocation Program.

28/ Data reflecting residues in processed grape products including wet and dry pomace, raisins and raisin waste processed from grapes bearing measurable weathered residues of phosmet must be submitted. If residues are found to concentrate in any of the processed commodities, appropriate food/feed additive tolerances must be proposed.

29/ A tolerance of 0.1 ppm (negligible residue) has been established for combined residues of phosmet and its oxygen analog in or on nuts. A tolerance of 10 ppm has been established for the same residues in or on almond hulls. The crop group tolerance for residues in or on nuts is not supported because data submitted on walnuts are inadequate (only two samples reflect a post-treatment interval of less than 61 days). Refer to footnote 31 for data needed to support a group tolerance.

30/ Data depicting residues in or on the nutmeats, a representative commodity of the tree nuts group (40 CFR 180.34), of walnuts following phosmet treatments according to the registered use on a nut crop likely to result in the highest residues (pecans). Tests must be conducted in CA where virtually all U.S.-grown walnuts are produced (Agricultural Statistics, 1984, p. 240). Alternatively separate tolerances of 0.1 ppm may be proposed for residues in or on almond and pecan nutmeats and the tolerance for residues in or on "nuts" revoked.

31/ A crop group tolerance is inappropriate at the present time for the following reason: use directions and tolerances must be proposed for additional group members rice, sorghum, and wheat.

32/ Data depicting residues in milled products and crude and refined oil processed from field corn bearing measurable weathered residues must be submitted. If residues are found to concentrate upon processing, appropriate food additive tolerances must be proposed. Treatment of the raw agricultural commodity with exaggerated rates may be necessary to obtain measurable residues prior to processing.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Residue Chemistry (footnotes continued).

33/ A crop group tolerance is inappropriate at the present time for the following reason: use directions and tolerances must be proposed and appropriate data submitted for residues in or on wheat forage, hay, and straw and one other cereal grains crop.

34/ A crop group tolerance is inappropriate at the present time for the following reason: use directions and tolerances must be proposed for one additional group member (clover).

35/ The available data indicates that residues of phosmet in or on alfalfa hay and forage following use of the registered formulations at the maximum rates will not exceed the established 40 ppm tolerance. 40 CFR §140.261 will be amended to delete the commodity entry "alfalfa" and add separate entries for "alfalfa forage and hay." Furthermore, the data indicate that a tolerance of 20 ppm would be adequate for alfalfa forage, if the registrant wishes to propose such a reduction.

36/ Data must be submitted to determine the residues in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues. It may be necessary to treat with exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration occurs in meal, hulls, or soapstock, appropriate food/feed additive tolerances must be proposed. The adequacy of the tolerance for residues in cottonseed oil will be assessed on receipt of these data.

37/ Presently, the nature of the residue in animals is not adequately understood. On receipt of the data requested in the section entitled "Nature of the Residue - Livestock," the appropriate nature of tolerances for residues in animal products will be determined. The adequacy of the available data regarding the magnitude of residues in animal products will not be determined until all requested data regarding metabolism in animals and magnitude of residues in feed items have been received. It should be noted that the available data indicate that phosmet and its oxygen analog transfer to the fat of ruminants sprayed with phosmet.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe For Data Submission 1/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,H	No	--	Yes 2/	9 Months
PHOTODEGRADATION						
161-2 - In Water	TGAI or PAIRA	A,B	No	--	Yes 2/	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No	--	Yes 2/	9 Months
161-4 - In Air	TGAI or PAIRA	A	No	--	No	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,H	Yes	00112304	No 2/	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	--	Yes 2/	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	-	--	-	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	-	--	-	
MOBILITY STUDIES:						
163-1 - Leaching and/or Adsorption/Desorption	TGAI or PAIRA	A,B,H	No	--	Yes 2/	12 Months
163-2 - Volatility (Lab)	TEP	A	No	--	Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No	--	Reserved 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data Submission[1]
§158.130 Environmental Fate (continued)						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No	--	Yes 2/	27 Months
164-2 - Aquatic (Sediment)	TEP	N/A	-	--	-	
164-3 - Forestry	TEP	N/A	N/A	--	-	
164-4 - Combination and Tank Mixes		N/A	N/A	--	-	
164-5 - Soil, Long-term	TEP	A	No	--	Reserved 4/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	--	Yes	39 Months
165-2 - Rotational Crops (field)	TEP	A	No	--	Reserved 5/	
165-3 - Irrigated Crops	TEP	N/A	N/A	--	N/A	
165-4 - In Fish	TGAI OR PAIRA	A,B	No	--	No 6/	
165-5 - In Aquatic Nontarget organisms	TEP	--	No	--	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data submission[1]
158.75 - OTHER EXPOSURE DATA						
Glove Permeability Studies		A,B	No	--	Yes 7/	6 months - acceptable protocol 14 months- final report

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

FOOTNOTES TO PREVIOUS TABLE

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§158.130 Environmental Fate

1/ Due dates refers to number of months following receipt of this Registration Standard or as otherwise stated.

2/ The June 29, 1984 Data Call-In (DCI) notice required registrants to submit this data under a specificed time schedule to satisfy the groundwater data requirements. The data submitted/cited in response to the DCI were found unacceptable except for aerobic soil studies.

3/ Contingent upon the results of the lab volatility study.

4/ Contingent upon residue dissipation rate in aerobic soil metabolism terrestrial and field dissipation studies. If residues from these studies do not reach 50 percent dissipation prior to subsequent treatment, a long term soil dissipation study is required.

5/ Required if significant residues of concern found in the confined study.

6/ Octanol/water coefficient < 1000; therefore this test is not required.

7/ Quantitative data must be submitted regarding the permeation and breakthrough time of chemical resistant gloves used as protective clothing and equipment for all liquid formulations. If these data are not available, they must be generated using methods described in American Society of Testing and Materials (ASTM) 739-81-Standard Test Method for Resistance of Protective Materials to Permeation by Hazardous liquid Chemicals. Because this type of testing is relatively new, it is recommended that testing protocols for permeation studies be submitted prior to initiation of any study.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission1/
§158.130 Environmental Fate (continued)						
Subpart K Reentry						
132-1 - Foliar Dissipation	TEP	A	No	—	Yes	Dec. 31, 1986 2/
132-1 - Soil Dissipation	TEP	A	No	—	No 3/	
133-3 - Dermal Exposure	TEP	A	No	—	No 4/	
133-4 - Inhalation Exposure	TEP	A	No	—	No 4/	

1/ Due dates refers to number of months following receipt of this Registration Standard or as otherwise indicated.

2/ The February 28, 1985 Data Call-In notice for reentry data requires foliar dissipation data by December 31, 1986.

3/ Required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil. Registrant has agreed to label potato use for machine harvest only therefore this test is not required.

4/ Not required if acceptable foliar dissipation data are submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibligraphic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission[1]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,H,I	Yes	00043470, 00046189, 00063196	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,H,I	Yes	00046190, 00063196, 00075439	No 2/	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,H,I	No	---	Yes	9 Months
81-4 - Primary Eye Irritation	TGAI	A,B,H,I	Yes	00063195, 00046192	No 2/	
81-5 - Primary Dermal Irritation	TGAI	A,B,H,I	Yes	00046191	No	
81-6 - Dermal Sensitization	TGAI	A,B,H,I	No	---	Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,H,I	Yes	00109652	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibligraphic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.135 Toxicology (continued)						
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A,B,H,I	Yes	00076436, 00076436	No 3/	
- Nonrodent (Dog)		A,B,H,I	Yes	00076436, 00076436	No 4/	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,H,I	No	—	Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,H,I	No	—	No 5/	
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B,H,I	No	—	No 5/	
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A,B,H,I	No	—	No 6/	
- Mammal	TGAI	A,B,H,I	No	—	No 6/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibligraphic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission
§158.135 Toxicology - (continued)						
CHRONIC TESTING:						
83-1 - Chronic Testing - 2 Species: - Rodent, and	TGAI	A,B,H,I	Yes	00076436	No	
- Nonrodent (Dog)		A,B,H,I	Yes	00076436	No	
83-2 - Oncogenicity - 2 Species: - Rat (preferred), and	TGAI	A,B.H.I	Partially	00076436	Yes	50 Months 7/ (8 months - progress report)
- Mouse (preferred)		A,B,H,I	Yes	00076436	No	
83-3 - Teratogenicity - 2 Species:	TGAI	A,B,H,I				
- Monkey			Yes	00053821, 00062649	No 2/	
- Rabbit			Yes	00062649, 00053821	No 2/	
83-4 - Reproduction - Rat 2 Generation	TGAI	A,B,H,I	Yes	00081432	No	
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,H,I	No	—	Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,B,H,I	No	—	Yes	12 Months
84-4 - Other Genotoxic Effects	TGAI	A,B,H,I	No	—	Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

FOOTNOTES TO PREVIOUS PAGES

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§158.135 Toxicology

1/ Due dates refers to number of months following receipt of this Registration Standard or as otherwise indicated.

2/ Collectively the studies satisfy the data requirement.

3/ A 2-year chronic toxicity/oncogenicity study in rats exists that satisfies the requirement for the 90-day rodent feeding study.

4/ A 2-year chronic toxicity study in dogs exists that satisfies the requirement for the 90-day nonrodent feeding study.

5/ Data base and exposure scenario do not trigger testing at this time.

6/ The acute delayed neurotoxicity and acute toxicity test did not indicate neurotoxic effects.

7/ A progress report is due 8 months after receipt of this Notice and semi-annually thereafter. A final report is due 50 months after receipt of this Standard.

8/ Submission of data is contingent upon the results of the rat oncogenicity study. If the oncogenicity study is positive, dermal penetration studies will be required.

9/ The Agency has received adverse effects/incidents concerning the use of phosmet as a flea dip (Paramite) on domestic pets (dogs and cats). The Agency is re-examining all studies concerning the toxicity and efficacy of this product to determine if additional data, labeling or other action is warranted regarding the continued registration of this product.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission1/
§158.145 Wildlife and Aquatic Organisms						
SPECIAL TESTING						
70-1 - Residue Level Monitoring	TGAI	A	No	--	Yes 2/	6 Months - Acceptable Protocol 18 months - Final Report
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,H,I	Yes	00084460	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,H,I	Yes	00034769	No 3/	
- Waterfowl	TGAI	A,H	Yes	00034769	No 3/	
71-3 - Wild Mammal Toxicity	TGAI	A	No		No 4/	
71-4 - Avian Reproduction						
- Upland Game Bird, and	TGAI	A	Yes	00125786	No 3/	
- Waterfowl	TGAI	A	Yes	00105999	No 3/	
71-5 - Simulated Field Testing	TEP					
- Mammals, and		A	No	--	No	
- Birds		A	No	--	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.145 Wildlife and Aquatic Organisms - (continued)						
- Actual Field Testing	TEP					
- Mammals		A	No	--	No	
- Birds		A	No	—	No	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI					
- Coldwater Fish Species, and		A,H,I	Yes	00063194, 00109135	No 5/	
- Warmwater Fish Species		A,H	Yes	00063194	No 5/	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,H,I	Yes	00063193, 00063194	No	
	TEP	A,H,I	No		Yes 6/	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A	No	--	Yes 7/	12 Months
- Mollusk	TGAI	A	No	--	Yes 7/	12 Months
- Shrimp	TGAI	A	No	--	Yes 7/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to satisfy This Requirement	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.145 Wildlife and Aquatic Organisms - (continued)						
72-4 - Fish Early Life Stage, and	TGAI	A	No	—	Yes 8/	15 Month
- Aquatic Invertebrate Life-Cycle	TGAI	A	No	—	Yes 8/	15 Months
72-5 - Fish - Life-Cycle	TGAI	A	No	—	Reserved 9/	
72-6 - Accumulation	TGAI	A	No	—	Reserved 9/	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A	No	—	Reserved 9/	
- Actual Field Testing - Aquatic Organisms	TEP	A	Partially	00054197	Reserved 9/	

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

FOOTNOTES FOR PREVIOUS PAGES

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§158.145 Wildlife and Aquatic Organisms

1/ Due dates refers to number of months following receipt of this Registration Standard or as otherwise indicated.

2/ Residue level monitoring data is required to support the registration of phosmet use on apples, corn, cotton, and alfalfa. Data on the residue levels on foliage, seeds, insects, and other avian and mammalian feed items in treatment areas is required. Also data on residue levels in runoff water, and in the water and sediments of representative streams and ponds in or near treatment areas is required. Monitoring should begin immediately after typical maximum-rate applications of phosmet to apple orchards, corn, cotton, and alfalfa crops. Monitoring should continue throughout the growing season and for six months after the last application. Monitoring must be done on a minimum of six sites selected to be representative of the various sites where the crops are grown. For corn, the selected sites must include sites from the corn belt and from the southern States. Registrants must submit protocols before beginning the studies.

3/ When used together, the data on the upland game bird and the waterfowl fulfill the data requirement.

4/ Data on wild mammal toxicity are not usually required. There are no special circumstances here to indicate that data should be required.

5/ When used together, the data on the coldwater species and the warmwater species fulfill the data requirement.

6/ Acute toxicity data on the end-use product is required when the EC_{50} of the technical grade of the active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use product is used as directed. In this case, the EC_{50} of the technical grade of the active ingredient is less than the EEC resulting from use on apples, corn, cotton, and alfalfa. Therefore, data on the formulated products registered for use on these crops are required.

7/ Data are required to support registrations for use on corn, cotton and citrus.

8/ Data are required because the pesticide use pattern is such that its presence in water is likely to be continuous or or recurrent, the LC_{50} and EC_{50} values for fish and aquatic invertebrates are less than 1 mg/L, and the estimated environmental concentrations in water is greater than 0.01 of the LC_{50} and EC_{50}s.

9/ The Agency reserves the option of requiring data in these categories, pending the outcome of the fish embryo-larvae, invertebrate life-cycle, and field monitoring tests.

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe For Data Submission 1/
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honeybee Acute Contact LD_{50}	TGAI	A,B,G	Yes	00066220	No	
142-2 - Honeybee - Toxicity of Residues of Foliage	TEP	A,B,G	Yes	00060625	No	
141-4 - Honeybee Subacute Feeding Study	[Reserved]1/					
141-5 - Field Testing for Pollinators	TEP	A,B,G	No	--	No2/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute Toxicity To Aquatic Insects	[Reserved]3/					
142-2 - Aquatic Insect Life-Cycle Study	[Reserved]3/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	[Reserved]3/					
143-1 Thru 143-2 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	[Reserved]3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR PHOSMET

FOOTNOTES FOR PREVIOUS TABLE

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§158.155 Nontarget Insect

1/ Reserved pending development of test methodology.

2/ Requirement for field studies is imposed only on a case-by-case basis. Data reviewed to date do not indicate the need for a field study.

3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSMET

Data Requirement	Composition[1]	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data Submission[2]
§158.120 Product Chemistry						
Product Identity and Composition:						
61-2 - Product Identity and Disclosure of Ingredients	MP	A,B,H,I	Partially	— [3]	Yes [4]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	A,B,H,I	Partially	—	Yes [5]	6 Months
61-3 - Discussion of Formation of Impurities	MP	A,B,H,I	No	—	Yes [6]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	MP	A,B,H,I	No	—	Yes [7]	12 Months
62-2 - Certification of Ingredient Limits	MP	A,B,H,I	No	—	Yes [8]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	A,B,H,I	Partially	00112317, 00112263 00126567, 00112314	Yes [9]	12 Months
Physical and Chemical Characteristics [10]						
63-2 - Color	MP	A,B,H,I	No	—	Yes	6 Months
63-3 - Physical State	MP	A,B,H,I	No	—	Yes	6 Months
63-4 - Odor	MP	A,B,H,I	No	—	Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSMET

Data Requirement	Composition[1]/	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Timeframe For Data Submission[2]
§158.120 Product Chemistry (continued)						
Product Identity and Composition:						
63-7 - Density, Bulk Density, or Specific Gravity	MP	A,B,H,I	No	--	Yes	6 Months
63-12 - pH	MP	A,B,H,I	No	--	Yes	6 Months
Other Requirement:						
64-1 - Submittal of Samples	MP	A,B,H,I	No	--	Reserved [11]/	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSMET

FOOTNOTES FOR PREVIOUS PAGES

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§158.120 Product Chemistry

1/ The 90% and 94% technical serve as the manufacturing-use products.

2/ Due dates refer to number of months following receipt of this Registration Standard or as otherwise indicated.

3/ Information is obtained from the product registration file for the 94% technical product.

4/ The following information on the 90% technical (476-2178) is required: the product name, trade name (if different), and any experimental or internal code number the company has assigned.

5/ The following information is required: (a) details of the manufacturing process, including the relative amounts of beginning materials; a description of the equipment used to produce the product; reaction conditions; the duration of each step of the process; purification procedures; and quality control measures for the 90% and 94% technical products; (b) the name and address of the manufacturer, producer or supplier of each beginning material used to manufacture the 90% technical. A copy of all technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier describes the composition and properties of each beginning material used to manufacture the 90% technical must also be submitted; (c) the address of the manufacturer, producer, or supplier of each beginning material used to manufacture the 94% technical.

6/ A discussion of each impurity believed to be present at $\geq$ 0.1% based on knowledge of the beginning materials, all possible chemical reactions, and any contamination is required for the 90% and 94% technical products.

7/ Five or more representative samples of the 90% and 94% technical products must be analyzed for the amount of active ingredient and each impurity present at $\geq$ 0.1% (w/w) using valid analytical methods.

8/ The following data are required for the 90% and 94% technical products: (a) upper and lower limits must be provided, validated, and certified; (b) upper limits must be provided, validated and certified for each toxicologically significant impurity present at <0.1% (w/w); (c) upper limits must be provided, validated and certified for each impurity present at $\geq$ 0.1% (w/w).

9/ Quantitative methods to determine the phosmet and all toxicologically significant impurities for which a certified limit must be submitted on the 90% and 94% technical products. Each method must be accompanied by validation studies of the precision and accuracy of the method.

10/ Adequate physical/chemical property information for the 90% and 94% technical products must be submitted unless otherwise indicated.

11/ If samples are needed the Agency will request them.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PHOSMET

Data Requirement	Test Substance 1/	Use Patterns	Does EPA Have Data?	Bibligraphic Citation	Must Additional Data be Submitted?	Timeframe For Data Submission[2]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,H,I	Yes	00043470, 00046189, 00063196	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,H,I	Yes	00046190, 00063196, 00075439	No 3/	
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,H,I	No	—	Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,H,I	Yes	00063195, 00046192	No 3/	
81-5 - Primary Dermal Irritation -Rabbit	MP	A,B,H,I	Yes	00046191	No	
81-6 - Dermal Sensitization -Guinea Pig	MP	A,B,H,I	No	—	Yes	9 Months

1/ Composition: MP= Manufacturing Use Product

2/ Due date refers to number of months following receipt of this Registration Standard or as otherwise indicated.

3/ Collectively the studies satisfy the data requirement.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation

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or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #) [40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
—Potassium salt of	F027	67923-62-0
—Sodium salt of	F027	3247-34-5
—Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
—Potassium salt of	F027	7778-73-6
—Sodium salt of	F027	131-52-2
—Zinc salt of	F027	2917-32-0
—Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
—Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
—2-Butoxyethyl ester	F027	19398-13-1
—Butoxypolypropoxypropyl ester	F027	53404-07-2
—Butoxypropyl ester	F027	25537-26-2
—Diethanolamine salt	F027	51170-59-3
—Diisopropanolamine salt	F027	53404-09-4
—Dimethylamine salt	F027	55617-85-1
—Dipropylene glycol isobutyl ether ester	F027	53535-26-5
—Ethanolamine salt	F027	7374-47-2
—2-Ethylhexyl ester	F027	53404-76-5
—Isooctyl ester	F027	53404-14-1

—Isopropanolamine salt	F027	53404-13-0
—Monohydroxylaluminum salt	F027	69622-82-8
—Polypropoxypropyl ester	F027	83562-66-7
—Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
—Sodium salt	F027	37913-89-6
—Triethanolamine salt	F027	17369-89-0
—Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
—Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
—Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
—Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
—Alkyl C-12 amine salt	F027	53404-84-5
—Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
—N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
—N,N-dimethyloleylamine salt	F027	53404-89-0
—N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
—Sodium salt	F027	13560-99-1
—Triethanolamine salt	F027	3813-14-7
—Triethylamine salt	F027	2008-46-0
—Alkyl (C3H7 - C7H9) ester	F027	
—Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
—2-Butoxyethyl ester	F027	2545-59-7
—Butoxypropyl ester	F027	1928-48-9
—Butyl ester	F027	93-79-8
—Dipropylene glycol isobutyl ether ester	F027	53535-31-2
—2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
—Propylene glycol isobutyl ether ester	F027	53466-86-7
—Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX APPENDIX

EPA Compendium of Acceptable Uses

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

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EPA Compendium of Acceptable Uses

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(0,0-DIMETHYL PHOSPHORODITHIOATE)

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c059201

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:
Tech (90%, 94%)
D (1%, 5%)
WP (7.5%, 12%, 12.5%, 50%, 70%)
Impr (15%)
EC (1 lb/gal, 3 lb/gal, 11.6%, 12.5%)
FlC (5 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: Do not plant any food or feed crop in rotation within 1 month after last application unless it is a registered use for phosmet. Crops registered for use with phosmet may be planted immediately following last application. Do not use water containing phosmet residues to irrigate crops used for food or feed which are not registered for use with phosmet.

Phosmet is incompatible with alkaline materials such as spray lime, lime sulfur, and bordeaux mixtures. These materials will reduce the insecticidal activity. Insecticidal activity may also be reduced when the water in the spray solution has a pH of 7 or higher. The pH of the spray solution may be corrected by the addition of a suitable buffering or acidifying agent for optimum insecticidal activity.

Protective Clothing Statements (Terrestrial Food Crop, Terrestrial Nonfood Crop, and Domestic Outdoor):

When mixing/loading wear mid forearm to elbow length chemical resistant gloves, long sleeve shirt, and long pants. During the application wear long sleeve shirt and long pants. Applicator must also wear a wide-brimmed hat during upward directed spraying to fruit and nut crops. Do not allow worker reentry into treated fields within 24 hours of application unless appropriate protective clothing is worn.

Bee Caution:

Phosmet is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply phosmet or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Agricultural Crop Tolerances (other than those listed in the text):

Cranberries	10 ppm
Nuts	0.1 ppm
Tomatoes	2 ppm

Livestock Tolerances:

Goats (fat, meat, meat byproducts)	0.2 ppm
Horses (fat, meat, meat byproducts)	0.2 ppm
Sheep (fat, meat, meat byproducts)	0.2 ppm

Endangered Species Restrictions:

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify their habitat is a violation of federal laws. The use of phosmet is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range.

*phosmet
Prolate
Imidan

GENERAL WARNINGS AND LIMITATIONS (continued)

Before using this pesticide in the following counties you must obtain the EPA Cropland Endangered Species Bulletin. The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the appropriate Regional Office of either U.S. Fish and Wildlife Service (FWS) or the U.S. Environmental Protection Agency. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE.

SPECIES	STATE	COUNTY
Alabama cavefish	AL	Lauderdale
Bayou darter	MS	Copia
Colorado squawfish	CO	Blanco, Delta, Garfield, Mesa, Moffat, Rio and Routt
Cui-ui	NV	Washoe
Freshwater mussels	AL	Colbert, Jackson, Marshall and Morgan
	AR	Clay, Clark, Cross, Lawrence, Randolph, Sharp and St. Francis
	KY	Ballard, Edmundson, Jackson, Laurel, Marshall, McCracken, Pulaski, Rockcastle, Warren and Wayne
Gila topminnow	AZ	Graham and Santa Cruz
Lahontan cutthroat trout	CA	Alpine, Mono, Nevada, Placer and Sierra
Leopard darter	AR	Sevier
Moapa dace	NV	Clark
Pahranagat	NV	Lincoln
Pahrump killifish	NV	Clark and White Pine
Slackwater darter	AL	Lauderdale, Madison and Limestone
Unarmored threespine stickleback	CA	Los Angeles and Santa Barbara
Woundfin	AZ	Mohave
	NV	Clark

Definition of Terms:

Tbls/tsp actual* (in dose column) - A hypothetical quantity computed by multiplying the number (or equivalent number) of tablespoons/teaspoons of product by the concentration of phosmet in the formulation.

** (in dose column) - Exact computation of actual dosage is not possible because of the lack of weight/volume information on the label. Extrapolation from other formulations reveals that the dosage from this label appears to fall within the range shown by formulations with known weight/volume ratios.

(in dose column) - Computed from tablespoons/teaspoons dosage.

Parenthized pest name - Claims for pest control limited to suppression of population are indicated by entirely parenthesized pest name.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		

General Warnings and Limitations: Unless otherwise specified, apply by aircraft or by ground equipment including concentrate and semiconcentrate equipment. When concentrate and semiconcentrate sprays are used, use proportionately lower volumes of water. In CA apply a minimum of 2 pounds per acre on mature pome and stone fruit trees and 1.75 pounds per acre on cherries.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/23001AA	Alfalfa		40 ppm 7 day preharvest/pregrazing interval through 1 pound per acre for foliar application in areas other than AZ, CA and NV. 14 day preharvest/pregrazing interval through 0.75 pound per acre for foliar application in AZ, CA, and NV. Do not make more than 1 application per cutting. Do not apply during bloom. Apply wettable powder formulations in 5 to 10 gallons of water per acre by aircraft and in 10 to 50 gallons of water per acre (20 to 50 gallons of water per acre in dense stands) by ground equipment. Apply emulsifiable concentrate formulation in a minimum of 10 gallons of water per acre by ground equipment. Use diluted emulsion within 3 hours after forming. Do not apply any sprays with a spreader-sticker.
IOABANA	Alfalfa blotch leafminer	1 lb/A (50%, 70% WP)	Use limited to areas other than AZ, CA and NV. Foliar application. For alfalfa blotch leafminer and meadow spittlebug, apply at first sign of infestation. For alfalfa weevil and Egyptian alfalfa weevil, apply when larvae are actively feeding or during periods of adult activity. For potato leafhopper in the Northeast and North Central States.
INASBWJ	Alfalfa weevil (adults)		
INASBWC	Alfalfa weevil (larvae)		
INASBTJ	Egyptian alfalfa weevil (adults)		
INASBTC	Egyptian alfalfa weevil (larvae)		
IRAEAKA	Meadow spittlebug		
IRAFAJA	Potato leafhopper		

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Alfalfa (continued)		
INASBWA	Alfalfa weevil	1 lb/A (3 lb/gal EC)	Foliar application. Apply when larvae are actively feeding.
INASBWC INASBTC	Alfalfa weevil (larvae) Egyptian alfalfa weevil (larvae)	0.75 lb/A (50% WP)	Use limited to AZ, CA and NV. Foliar application. Apply when larvae are actively feeding.
IRACALA	Pea aphid	0.75 lb/A (50% WP)	Use limited to AZ, CA and NV. Foliar application. Tank mix with dimethoate.
		1 lb/A (50% WP)	Use limited to areas other than AZ, CA and NV. Foliar application. Tank mix with dimethoate.
/03001AA	Almond		0.1 ppm (N) (nuts) 10 ppm (almonds, hulls) 30 day preharvest interval through 6 pounds per acre for foliar application. For bearing almonds, make only 1 foliar application per season.
ITAMABA	Peach twig borer	0.5 lb/100 gal [max 3 lb/A] (50% WP)	Foliar application. Apply as a full cover spray when infestation starts.
ITAMABA IRAKBYA	Peach twig borer San Jose scale	0.5-0.525 lb/100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04001AA	Apple		10 ppm 7 day preharvest interval through 4 pounds per acre for foliar application.
IRACAUA	Apple aphid	0.5-0.75 lb/ 100 gal [max 4 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/ tree] (12.5%, 50% WP) or 0.083-0.125 oz#/gal (12.5% EC)**	Foliar application. Apply as a full cover spray. For heavy infestations use the higher rate. Repeat as needed. For elm spanworm, fruittree leafroller, green fruitworm, gypsy moth, Obliquebanded leafroller in the northeast. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program.
IOBMAQA	Apple maggot		
ITBUCSA	Codling moth		
ITANAHA	Elm spanworm		
ILAVASA	(European red mite)		
INBUAGA	Fruittree leafroller		
ITBCBSA	Green fruitworm		
ITAXAIA	Gypsy moth		
INBPAZA	Japanese beetle		
ITBUAVA	Obliquebanded leafroller		
ITBUALA	Orange tortrix		
INASAVA	Plum curculio		
ITBUAPA	Redbanded leafroller		
IRACBQA	Rosy apple aphid	0.45-0.6 tbls actual*/gal (7.5%, 12% WP)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.
IQAMATA	(Tarnished plant bug)		
ILAVBEA	(Twospotted spider mite)		
IRACAUA	Apple aphid	0.25-0.5 lb/ 100 gal [350-400 gal/A] (50% WP)	Use limited to the northeast. Foliar application. Do not apply to early MacIntosh or Wealthy varieties. Repeat as needed. Tank mix with methomyl.
IOBMAQA	Apple maggot		
ITBUCSA	Codling moth		
ITANAHA	Elm spanworm		
ILAVASA	European red mite		
INBUAGA	Fruittree leafroller		
ITBCBSA	Green fruitworm		
ITAXAIA	Gypsy moth		
INBPAZA	Japanese beetle		
ITBUAVA	Obliquebanded leafroller		
ITBUALA	Orange tortrix		
INASAVA	Plum curculio		
ITBUAPA	Redbanded leafroller		
ITBDAIA	Redhumped caterpillar		
IRACBQA	Rosy apple aphid		
IQAMATA	Tarnished plant bug		
ITAPABA	Tentiform leafminer		
ITBUBJA	Tufted apple bud moth		

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(0,0-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple (continued)		
	Pest list continued from previous page.		
ILAVBEA	Twospotted spider mite		
IRAFBAA	White apple leafhopper		
IRAKBYA	San Jose scale	0.5-0.525 lb/ 100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
IRAFBAA	White apple leafhopper	0.525-0.7 lb/ 100 gal (70% WP)	Use limited to MI. Foliar application. Tank mix with pyrethrins.
/05001AA	Apricot		5 ppm 14 day preharvest interval through 3.15 pounds per acre for foliar application.
IOBMAQA	Apple maggot	0.5-0.75 lb/ 100 gal [max 3.15 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/ tree] (12.5%, 50% WP) or 0.083-0.125 oz#/gal (12.5% EC)**	Foliar application. Apply as a full cover spray. For heavy infestations use the higher dosage rate. Repeat as needed. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program.
ILAVASA	(European red mite)		
ITBUCJA	Oriental fruit moth		
ITAMABA	Peach twig borer		
INASAVA	Plum curculio		
ITBUAPA	Redbanded leafroller		
ILAVBEA	(Twospotted spider mite)		
		0.45 tbls actual*/gal (7.5% WP)	Delayed dormant and foliar application. Formulated with captan.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apricot (continued)		
TAMABA RAKBYA	Peach twig borer San Jose scale	0.5-0.525 lb/ 100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
01009AA	Blueberry		10 ppm 3 day preharvest interval through 1 pound per acre for foliar application.
IOBMAPA TBMAGA NASAVA	Blueberry maggot Cranberry fruitworm Plum curculio	1 lb/150-200 gal/A (50% WP)	Use limited to the Northeastern United States. Foliar application. A second application may be made when indicated by insect infestations and local or state spray programs.
05002AA	Cherry, Sour (Tart)		10 ppm (cherries) 7 day preharvest interval through 1.75 pounds per acre for foliar application.
IOBMALA ILAVASA INBUAGA INBPAZA ITAMABA INASAVA ILAVBEA	Cherry fruit fly (European red mite) Fruittree leafroller Japanese beetle Peach twig borer Plum curculio (Twospotted spider mite)	0.5-0.525 lb/ 100 gal [max 1.75 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/ tree] (12.5%, 50% WP)	Foliar application. Apply as a full cover spray. Repeat as needed. For cherry fruit fly, fruittree leafroller, and plum curculio in the Northeast. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program.
		0.45-0.72 lb/ gal (7.5%, 12% WP)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cherry, Sour (Tart) (continued)		
TAMABA RAKBYA	Peach twig borer San Jose scale	0.5-0.525 lb/ 100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
02000AA	Citrus Fruits (foliar treatment)		5 ppm (citrus fruit) This use occurs on Special Local Need (24-C) labeling. Refer to appropriate labeling for use information and limitations.
28005AA	Corn		0.5 ppm (corn, fresh (inc. sweet K+CWHR) 0.5 ppm (corn, grain) 10 ppm (corn, fodder) 10 ppm (corn, forage) 14 day preharvest interval through 0.5 pound per acre for foliar application.
NAMBHJ	Corn rootworms (adult)	0.25-0.5 lb/A (50% WP)	Use limited to the Corn Belt. Foliar application. Apply in 2 to 5 gallons of water per acre by aircraft and in 20 to 50 gallons of water per acre by ground equipment. Apply when beetles are present in sufficient numbers to warrant treatment for protection of the silk from adult feeding.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28007AA	**Cotton**		0.1 ppm (cottonseed) 0.2 ppm (cottonseed oil) 21 day preharvest interval through 1 pound per acre for foliar application. Do not apply more than 10 pounds per acre per season. Do not graze or feed forage to livestock. Do not apply in Claiborne and Copiah counties, MS; Lauderdale and Madison counties, AL; and Laurence county, TN. Do not apply within 1 mile of any coastal or estuarine waters. Do not apply within 100 feet of other aquatic habitats.
INASAHA	Boll weevil	0.5 lb/A [3-5 gal/A by aircraft] or 0.25-0.5 lb/A [5-20 gal/A by ground equipment] (50% WP)	Use limited to areas other than the San Joaquin Valley, CA. Foliar application. Apply to overwintering generations. Make the first application at the one-third square stage and the second application 5 to 7 days later. When applying by ground equipment, use the higher rate for heavy infestations.
		0.75-1 lb/A (50% WP)	Use limited to areas other than the San Joaquine Valley, CA. Foliar application. Apply in 3 to 5 gallons of water per acre by aircraft and in 5 to 20 gallons of water by acre by ground equipment. For first, second, and third generation, apply at 3 to 7 day intervals depending upon weevil populations and weevil migration. Use the higher rate for heavy infestations. Check infestations regularly.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01014AA	Grapes		10 ppm 7 day preharvest interval through 1.5 pounds per acre (dust) or 1 pound per acre (wettable powder) for foliar application. 14 day preharvest interval through 1.5 pounds per acre (wettable powder) for foliar application. Do not apply when fruit or cover crops are in bloom. Spray or dust both sides of each row and spray the tops of the vines for thorough coverage.
ITBUCWA IRAFAOA INBPAZA	Grape berry moth Grape leafhopper Japanese beetle	1-1.5 lb/200 gal/A (50%, 70% WP) or 0.375 tbls actual*/gal (12.5% WP)	Delayed dormant and foliar application. For use in the east. For grape berry moth, apply prebloom, postbloom, first, and later cover sprays, as needed. For grape leafhopper, apply when most nymphs hatch (generally coincides with grape berry moth). For Japanese beetle, use the higher rate.
ITBMATA ITBUBCA	Grape leaffolder Omnivorous leafroller	1.5 lb/A (5% D)	Use limited to CA. Foliar application. Apply between egg hatch and pupation.
		1 lb/200 gal/A (50%, 70% WP) or 0.375 tbls actual*/gal (12.5% WP)	Foliar application. For use in the west. Apply between egg hatch and pupation.
		0.45-0.6 tbls actual*/gal (7.5%, 12% WP)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.
/06018AA	Kiwi Fruit (soil treatment)		25 ppm This use occurs on Special Local Need (24-C) labeling. Refer to appropriate labeling for use information and limitations.

EPA Compendium of Acceptable Uses

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/0200-AA /02006AA	Lemon Orange		5 ppm (citrus fruits) 7 day preharvest interval through 15 pounds per acre for foliar application. Do not make more than 3 applications per season.
IRAFAGA IRAKAEA	Brown soft scale California red scale	0.5 lb/100 gal [max 15 lb/A] (50% WP)	Use limited to AZ, CA, and TX. Foliar application. Apply as a full cover spray. Make up to 3 applications per season. Allow 30 days between applications. Tank mix with a suitable horticultural spray oil.
/05003AA	Nectarines		5 ppm 14 day preharvest interval through 3 pounds per acre for foliar application. Do not tank mix with propargite on late maturing nectarines as fruit injury may result.
IOBMAQA ILAVASA ITBUCJA ITAMABA INASAVA ITBUAPA ILAVBEA	Apple maggot (European red mite) Oriental fruit moth Peach twig borer Plum curculio Redbanded leafroller (Twospotted spider mite)	0.5-0.75 lb/100 gal [max 3 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/tree] (12.5%, 50% WP) or 0.083-0.125 oz#/gal (12.5% EC)**	Foliar application. Apply as a full cover spray. For heavy infestations use the higher rate. Repeat as needed. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program.
		0.45 tbls actual*/gal (7.5% WP)	Delayed dormant and foliar application. Formulated with captan.
ITAMABA IRAKBYA	Peach twig borer San Jose scale	0.5-0.525 lb/100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
	Orange		See Lemon cluster.

EPA Compendium of Acceptable Uses

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/05003AA	Peach		10 ppm 14 day preharvest interval through 3 pounds per acre for foliar application.
ILAVASA	(European red mite)	0.5-0.75 lb/ 100 gal [max 3 lb/A] (50%, 70% WP) or 0.375-1 tbls/ gal [max 10 gal/ tree] (12.5%, 50% WP) or 0.083-0.125 oz#/gal (12.5% EC)**	Foliar application. Apply as a full cover spray. For heavy infestations use the higher rate. Repeat as needed. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program. Do not use emulsifiable concentrate on peaches that are to be dried.
INBPAZA	Japanese beetle		
ITBUCJA	Oriental fruit moth		
ITAMABA	Peach twig borer		
INASAVA	Plum curculio		
IQAMATA	Tarnished plant bug		
ILAVBEA	(Twospotted spider mite)		
		0.45-0.6 tbls actual*/gal (7.5%, 12% WP)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.
ITAMABA	Peach twig borer	0.5-0.525 lb/ 100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
IRAKBYA	San Jose scale		
/04003AA	Pear		10 ppm 7 day preharvest interval through 5 pounds per acre for foliar application.
IRACAUA	Apple aphid	0.5-0.75 lb/ 100 gal [max 5 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/ tree] (12.5% EC)** or	Foliar application. Apply as a full cover spray. For heavy infestations use the higher dosage rate. Repeat as needed. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program. For elm spanworm, gypsy moth, and fruittree leafroller in the Northeast.
ITBUCSA	Codling moth		
ITANAHA	Elm spanworm		
ILAVASA	(European red mite)		
INBUAGA	Fruittree leafroller		
ITAXAIA	Gypsy moth		
IRAXALA	Pear psylla		
INASAVA	Plum curculio		
ITBUAPA	Redbanded leafroller		
IRACBQA	Rosy apple aphid		

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Peas (continued)		
	Pest list continued from previous page.		
IQAMATA	(Tarnished plant bug)	0.083-0.125 oz#/gal (12.5% EC)**	
ILAVBEA	(Twospotted spider mite)		
		0.45-0.6 tbls actual*/gal (7.5%, 12% EC)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.
IRAKBYA	San Jose scale	0.5-0.525 lb/100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.
/28016AA	**Peas**		0.5 ppm (peas) 10 ppm (peas, forage) 10 ppm (peas, hay) 7 day preharvest/pregrazing interval through 1 pound per acre for foliar application (peas and peas, forage). 10 day preharvest interval through 1 pound per acre for foliar application (peas, hay).
INASDPA INAGADA	Pea leaf weevil Pea weevil	0.75-1 lb/A (50% WP)	Use limited to the Pacific Northwest states. Foliar application. Apply in 5 to 10 gallons of water per acre by aircraft and in 20 to 50 gallons of water per acre by ground equipment. Apply between emergence and early pod formation when adult populations are present but before eggs are laid.

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(0,0-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/03003AA	Pecan		0.1 ppm (N) (nuts) 14 day preharvest interval through 0.75 pound per 100 gallons for foliar application. Do not graze livestock on cover crops grown in treated pecan groves.
ITBUCCA ITBMADA INASBBA	Hickory shuckworm Pecan nut casebearer Pecan weevil	0.75 lb/100 gal (50% WP)	Foliar application. Apply as a full cover spray when infestation starts. Repeat as needed. For pecan weevil, repeat at 7 day intervals. For pecan nut casebearer in TX.
/05005AA /05004AA	Plum Prune		5 ppm (plums (fresh prunes)) 7 day preharvest interval through 3 pounds per acre for foliar application.
IOBMAQA ITBUCSA ILAVASA ITBUCJA ITAMABA INASAVA ITBUAPA ITBDAIA ILAVBEA	Apple maggot Codling moth (European red mite) Oriental fruit moth Peach twig borer Plum curculio Redbanded leafroller Redhumped caterpillar (Twospotted spider mite)	0.5-0.75 lb/100 gal [max 3 lb/A] (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/tree] (12.5%, 50% WP) or 0.083-0.125 oz#/gal (12.5% EC)**	Foliar application. Apply as a full cover spray. For heavy infestations use the higher rate. Repeat as needed. Usually suppresses European red mite and twospotted spider mite when used in a seasonal program.
		0.45-0.6 tbls actual*/gal (7.5%, 12% WP)	Delayed dormant and foliar application. Formulated with captan or zineb and captan.
ITBUCSA	Codling moth	0.5 lb/100 gal [max 3 lb/A] (50% WP)	Foliar application. Apply by ground equipment. For use in CA.
ITAMABA IRAKBYA	Peach twig borer San Jose scale	0.5-0.525 lb/100 gal (50%, 70% WP)	Use limited to the Pacific Coast States. Delayed dormant application. Apply for thorough coverage by ground equipment. Tank mix with a suitable horticultural oil.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/14013AA	Potato		0.1 ppm 7 day preharvest interval through 1 pound per acre for foliar application. Use limited to areas other than CA. Apply in sufficient water for thorough coverage.
INAMCFA	Colorado potato beetle	0.75-1 lb/A (50% WP)	Foliar application. For use in the Northeast.
INAMBSA	Potato flea beetle		
INAMCFA	Colorado potato beetle	1 lb/A (50%, 70% WP)	Foliar application.
INAMBSA	Potato flea beetle		
IRAFAJA	Potato leafhopper		
	Prune		See Plum cluster.
	TERRESTRIAL NON-FOOD CROP		
	(Ornamental Plants and Forest Trees)		
/30005AA	Christmas Tree Plantations		This use occurs on Special Local Need (24-C) labeling. Refer to appropriate labeling for use information and limitations.
/30097AA	Loblolly Pine (seedlings)		
/30104AA	Slash Pine (seedlings)		Wear rubber gloves during treating and planting. Some slight needle burn and first year growth reduction may occur following treatment to loblolly pine.
/30135AA	White Pines (seedlings)		
INASBRA	Pales weevil	4% top dip [5 gal/ 10,000 seedlings] (50%, 70% WP)	Foliar application. Dip treatment down to and including the root collar only. Avoid coverage of roots. Dip loose enough to allow the suspension to penetrate the bundles. Swish the tops for 10 to 15 seconds. Drain and allow the seedlings to dry before planting. The addition of an extender may help under high rainfall conditions.
INASCVA	Pitch-eating weevil		

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/35000AA /24000AA /63000OA	Ornamental and/or Shade Trees Ornamental Shrubs		Choose a cool calm period, preferably in the early morning or evening. Do not apply if rain is expected or before plant surfaces are dry. Do not use on Washington hawthorne.
IRACATA IRACDHA IRACGTA IRACCHA IRACBUA	Apple aphid Beech blight aphid Maple aphids Rose aphids Woolly apple aphid	0.25-0.5 lb/ 100 gal or 50 gal by mist blower or 0.042-0.083 oz#/gal (1 lb/gal EC)	Foliar application. Apply for thorough coverage when pests first appear. Spreader-stickers may be added to the spray.
ISBEAMB ILAVASA IRAWAAA IRAZALA	Birch leafminer European red mite Mealybugs Pine bark adelgid	0.5 lb/100 gal or 50 gal by mist blower or 0.042 oz/gal (1 lb/gal EC)	
INBUAGA ITCHADA ILAVBEA	Fruittree leafroller Mimosa webworm Twospotted spider mite	0.75 lb/100 gal or 50 gal by mist blower or 0.125 oz#/gal (1 lb/gal EC)	
ISBEAMB ITAUAEA INAMDAC ITANAHA ITAXAIA INBPAZA ITBDAIA ITANAVA	Birch leafminer Eastern tent caterpillar Elm leaf beetle (larvae) Elm spanworm Gypsy moth Japanese beetle Redhumped caterpillar Spring cankerworm	0.5-0.75 lb/ 100 gal (50%, 70% WP) or 0.375-1 tbls actual*/gal [max 10 gal/ tree] (12.5%, 50% WP)	Foliar application. Apply for thorough coverage. For heavy infestations use the higher rate. For birch leafminer, elm spanworm, gypsy moth, and spring cankerworm in the northeast. Repeat as needed.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Ornamental and/or Shade Trees cluster (continued)		
INATDAA	Elm leaf beetle	0.5-0.75 lb/ 100 gal or 50 gal by mist blower or 0.083-0.125 oz#/gal (1 lb/gal EC)	Foliar application. Apply for thorough coverage when pests first appear. Spreader-sticker may be added to the spray. Apply the lower rate for early instars.
ITANAZA	Elm spanworm		
ITANACA	Fall cankerworm		
ITABAZA	Fall webworm		
ITAUAGA	Forest tent caterpillar		
ITALALA	Gypsy moth		
INBPAZA	Japanese beetle		
INANEMA	Poplar-and-willow leaf beetle		
ITANAVA	Spring cankerworm		
/30124AA	Western Pines		Use limited to the Pacific Northwest United States.
ITBUDDA	European pine shoot moth	1 lb/A or 1 lb/100 gal for individual trees (50% WP)	Foliar application. Apply for thorough coverage. Repeat at 14 day intervals throughout the flight period of the moths.
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)		
/680000A	Wide Area and General Outdoor Treatments		
ISASAYA	Fire ant	0.135 oz/gal [1 gal/ mound] or 0.135 oz/gal [2 gal/ mound over 22 in.] (50% WP)	Use limited to TX. Mound treatment. Apply as a gentle rain. Thoroughly wet the mound and surrounding area to a 4 foot diameter (12.5 square feet). Apply when temperatures are between 65 to 85 F (18.3 to 29.4 C) or in the early morning or late evening hours. Treat mounds as they appear.

DOMESTIC OUTDOOR

(Ornamental Plants and Forest Trees)

/630030A	Domestic Dwellings, Outdoor	Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Ornamental and/or Shade Trees cluster for use information and limitations.

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	INDOOR		
	(Agricultural Crops)		
/14018EA	Sweet Potato		10 ppm Wash sweet potatoes in clean water before marketing.
INASBGA	Sweet potato weevil	0.1-0.2 oz/ 50 lb (5% D)	Stored commodity treatment. Make 1 application as soon as possible before storage. Thoroughly cover all surfaces using suitable dusting equipment.

(Pets and Domestic Animals)
(Animals and Their Man-Made Premises)

General Warnings and Limitations: Applicators must wear long sleeved shirt, long pants, elbow length waterproof gloves, waterproof apron, and unlined waterproof boots.

/53001IA	Beef Cattle		0.2 ppm (cattle (fat, meat, and meat byproducts)) 21 day preslaughter interval for 5 percent animal dust bag treatment; 0.04 ounce per animal for animal dust treatment; 2.5 pounds per 100 gallons animal dip treatment (0.24 to 0.3 percent dip replenishment); 1 gallon per animal, 0.25 percent animal spray treatment; and 1 fluid ounce of 6 percent animal pour on treatment per 100 pounds of bodyweight. 3 day preslaughter interval through 0.5 pound per 100 gallons animal dip treatment (0.03 to 0.06 percent dip replenishment) and 1.25 pounds per 100 gallons spray. Do not treat sick or debilitated animals. Place a board baffle behind the dust bags if they are used near feed or water. Do not use within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip animals that are over-

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beef Cattle (continued)		
			heated. Do not treat calves less than 3 months of age, except in federal eradication programs. Hand dipping of young animals will prevent the animal from swallowing the dip emulsion.
IOAWABA IMAAADA	Cattle grubs* Lice	6% pour on [1 fl.oz/100 lb body-weight] (1 lb/gal EC)	Animal pour on treatment. Apply down the center line of the animals' back. For cattle grubs, treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal. Rapid kill of large numbers of larvae in these tissues may cause toxic side effects such as bloat, salivation, staggering and paralysis. Treat for other pests any time of the year except when cattle grubs are in the gullet or spinal canal. Repeat at 7 to 10 day intervals as needed.
IOAWABA ILAMAGA IOAUADA IMAAADA ILAMAHA	Cattle grubs* Cattle tick Horn fly Lice Southern cattle tick	0.25% spray [1 gal/animal and proportionately smaller quantities for younger animals] (1 lb/gal EC)	Animal spray treatment. Apply with a high pressure spray, taking care to wet the skin. Apply to the point of runoff. For cattle grubs, treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal. Rapid kill of large numbers of larvae in these tissues may cause toxic side effects such as bloat, salivation, staggering and paralysis. Treat for other pests any time of the year except when cattle grubs are in the gullet or spinal canal. Repeat at 7 to 10 day intervals as needed.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beef Cattle (continued)		
IOAWABA ILAMAGA ILASADA IMAAADA ILAMAHA	Cattle grubs* Cattle tick Itch mite Lice Southern cattle tick	0.2% dip and 0.24% dip replenishment (1 lb/gal EC)	Animal dip treatment. Add super phosphate to control the pH of the emulsion. For cattle grubs, treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal. Rapid kill of large numbers of larvae in these tissues may cause toxic side effects such as bloat, salivation, staggering and paralysis. Treat for other pests any time of the year except when cattle grubs are in the gullet or spinal canal. Repeat at 7 to 10 day intervals as needed. Replenish the dip each time the vat's volume is reduced by 0.25 of its initial volume. Change the vat dip emulsion each time 1 of the following occurs: 1) when the vat has been charged for 60 days; 2) when dip becomes too foul; 3) if the number of animals dipped equals the number of gallons in the initial volume.
IOAUAEA IOAUADA	(Face fly) Horn fly	0.01 oz/adult animal and proportionately smaller quantities for younger animals] (1% D)	Animal dust treatment. Apply to upper portions of back, neck, and poll. Rub in lightly. Repeat as needed.
IOAUAEA IOAUADA IMAAADA	(Face fly) Horn fly Lice	dust bag (1% D)	Animal dust bag treatment. Forced Use: Put dust in dust bags and hang in barn door exits or alleyways leading from animal buildings. Hang near salt or mineral blocks or watering holes. Protect dust bags from weather. Free Choice Use: Place dust bags in loafing sheds, holding pens, feedlots, near watering holes or other areas where cattle gather.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beef Cattle (continued)		
IOAUADA	Horn fly	dust bag (5% D)	Animal dust bag treatment. Suspend dust bags near salt boxes, loafing sheds or near feed and water facilities. For mandatory use, suspend dust bags across a gate between pasture and water or between pasture and feeding areas. Hang the dust bags at a height so that the lower portions hit the head, shoulders, and backline of the animal.
IMAAADA	Lice	0.005 oz/100 lb body-weight [max 0.04 oz/animal] (1% D)	Animal dust treatment. Apply to upper portions of back, neck, and poll. Rub in lightly. Repeat as needed.
			* - The use of phosmet to control cattle grubs is considered a new animal drug use requiring a new animal drug application with FDA. This use is no longer regulated by EPA.
		Refer to Dairy Cattle (non-lactating) for additional use and limitation information.	
/54002IA	**Cats**		
			Improper dilution of emulsifiable concentrate dip can cause serious injury to cats. Do not treat kittens under 8 weeks of age.
IMNAAAA ILAAACA	Fleas Ticks	0.5 fl.oz 11.6% EC/gal (11.6% EC)	Animal treatment. Dip or sponge on emulsion until the skin is wet. Allow the emulsion to dry on the animal. Repeat at 7 day intervals as needed. Controls fleas for up to 9 days and ticks for up to 16 days.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/50001IA /53001IA	Dairy Cattle (non-lactating)		28 day prefreshening interval through 2.5 pounds per 100 gallons dip (0.25 to 0.3 percent dip replenishment) and 1.25 pounds per 100 gallons spray. If freshening should occur within the 28 day period after treatment, that milk must be destroyed. Do not apply to animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. Consult a veterinarian at the first sign of adverse reaction. Do not treat sick, convalescent, or stressed animals or calves less than 3 months old. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty or overheated animals. Following dipping, allow animals adequate space and ventilation to thoroughly dry. Do not allow animals to become crowded or overheated. Although claims for cattle grubs are not made for the 5 pound per gallon flowable concentrate formulation, it is important to treat cattle before or after grub larvae are in the gullet or spinal canal. Killing of larvae in these tissues may cause host-parasite reactions such as bloat, salivation, staggering, and paralysis. Consult a veterinarian, extension livestock specialist, or extension entomologist regarding timing of treatment to avoid host-parasite reactions. DIP VAT PROCEDURE. Prior to charging the vat, empty out the old contents and thoroughly clean the vat. Add water and mix the desired dilution thoroughly with a compressed air device or other suitable means. Restir vat contents prior to each use. DIP VAT REPLENISHMENT. During the dipping operation, each time the vat's volume is reduced by 12.5 to

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Dairy Cattle (non-lactating) (continued)		
			25 percent of its initial volume, replenish the vat at the initial charge dilution. For evaporation add additional water accordingly. For added water due to rainfall, merely replenish the vat with phosmet at the initial charge dilution. If overflow occurs either analyze for phosmet content and adjust accordingly or dispose of vat contents and recharge. VAT MAINTENANCE. Phosmet concentration test kits may be used to maintain the vat dilution. If no test kit is available the vat should be emptied, cleaned, and recharged each time the following occurs: 1) When the vat has been charged for 120 days. 2) When the dip becomes too foul. 3) If the number of animals dipped equals twice the number of gallons of the initial bath volume within the 120 day limit.
ILAMAGA ILAMAHA	Cattle tick Southern cattle tick	0.5 lb/100 gal dip and 0.03-0.06% dip replenishment (5 lb/gal FlC)	Animal dip treatment. For general use.
ILAMAGA IOAUADA	Cattle tick Horn fly	0.5 lb/100 gal spray (5 lb/gal FlC)	Animal spray treatment. Apply as a high pressure spray, taking care to wet the skin. Apply to the point of runoff.
ILAMADA	Gulf Coast tick	1.25 lb/100 gal spray (5 lb/gal FlC)	
IMAAADA	Lice	0.83 lb/100 gal spray (5 lb/gal FlC)	

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Dairy Cattle (non-lactating) (continued)		
ILAMADA	Gulf Coast tick	1.25 lb/100 gal dip and 0.1-0.15% dip replenishment (5 lb/gal FlC)	Animal dip treatment. For feedlot use. Repeat at 7 to 10 day intervals as needed. Treatment for itch mite may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Treatment for itch mite may be made any time 7 to 10 days following cattle grub treatment. For control of itch mite make 2 applications 10 to 14 days apart.
IOAUADA	Horn fly	0.625 lb/100 gal dip and 0.06-0.075% dip replenishment (5 lb/gal FlC)	
ILASADA	Itch mite	2.5 lb/100 gal dip and 0.25-0.3% dip replenishment (5 lb/gal FlC)	
IMAAADA	Lice	0.83 lb/100 gal dip and 0.075-0.1% dip replenishment (5 lb/gal FlC)	
/54003IA	**Dogs**		Improper dilution of emulsifiable concentrate dip can cause serious injury to dogs.
IMNAAAA ILASAAA ILAAACA	Fleas (Sarcoptc mange mites) Ticks	flea collar (15% Impr)	Animal treatment. Buckle collar around dogs' neck. Collar should be worn losely to prevent irritation. Allow 2 to 3 fingers between the collar and neck. Cut off excess length. When first worn check for irritation. Remove at the first

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Dogs (continued)		
			sign of irritation. Do not use on sick or convalescing dogs or puppies under 12 weeks of age. Remove collar when bathing. Controls fleas and ticks for up to 7 months and aids in control for an additional 3 months. Aids in the prevention of sarcoptic mange mites for up to 8 weeks. Replace when effectiveness diminishes.
IMNAAAA ILAAACA	Fleas Ticks (including American dog tick and brown dog tick)	0.025 g/lb of bodyweight (5% D)	Animal treatment. Apply liberally over the animal beginning at the head and rub thoroughly into the hair to the skin. Treat legs and feet and minimize treatment around the eyes and face. Do not treat puppies under 12 weeks of age. Controls fleas for up to 21 days and ticks for up to 14 days.
		1 fl.oz 11.6% EC/gal (11.6% EC)	Animal treatment. Dip or sponge on emulsion until the skin is wet. Allow the emulsion to dry on the animal. Repeat at 7 day intervals as needed. Do not treat puppies under 8 weeks of age. Controls fleas and ticks for up to 16 days.
ILASAAA	Sarcoptic mange mites	0.025 g/lb bodyweight (5% D)	Animal treatment. Treat entire dog paying particular attention to infected areas and rub thoroughly into hair to the skin. Make 3 applications at 7 day intervals. If no improvement is observed in 21 days, consult a veterinarian.
		1 fl.oz 11.6% EC/gal (11.6% EC)	Animal treatment. Dip the dog until the skin is wet and allow to shake dry. Do not rinse. If no improvement is seen within 14 days, consult a veterinarian. If the dog becomes reinfested, retreatment may be needed.

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
3300.1A	Swine		0.2 ppm (hogs (fat, meat, and meat byproducts) 1 day preslaughter interval through 0.01 ounce per animal for animal dust treatment.
IMAAADA	Lice	0.005-0.01 oz/animal (1% D)	Animal dust treatment. Apply to the backline and lightly rub in. Repeat at 10 to 14 day intervals or as needed.

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
9001500 AAAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops)	All sites
9900300 AAAAAAA	Tank Mix		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops)	Alfalfa, Almond, Apple, Apricot, Cherry Sour (Tart), Lemon, Nectarine, Orange, Peach, Pear, Plum, Prune

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

Listing of Registered Pesticide Products by Formulation

&090.0001 90% technical chemical
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000476-02178*
*currently unavailable for review

&094.0001 94% technical chemical
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000476-02177

&001.0003 1% dust
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
002724-00278

&005.0003 5% dust
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000400-00353 000476-02058 000476-02116 002724-00226
002724-00277 028293-00015

&007.5006 7.5% wettable powder
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201) plus captan (081301)
000226-00249

&012.0006 12% wettable powder
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201), zineb (014506) plus captan (081301)
000842-00109

&012.5006 12.5% wettable powder
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000476-02161

&050.0006 50% wettable powder
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000476-01917 000476-02112 002749-00162** 020954-00014
**suspended

&070.0006 70% wettable powder
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
000476-02158

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

Listing of Registered Pesticide Products by Formulation (continued)

&015.0010 15% impregnated materials
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
002724-00279

&101.0012 1 lb/gal emulsifiable concentrate
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201) plus aromatic petroleum distillate (006601)
000476-02043* 002724-00169* 002724-00262*
*currently unavailable for review

N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201) plus petroleum distillate (063503)
000476-02167 000476-02217

&103.0012 3 lb/gal emulsifiable concentrate
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201) plus xylene range aromatic solvent (086803)
000476-02033

&211.6012 11.6% emulsifiable concentrate
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
002724-00169

&212.5012 12.5% emulsifiable concentrate
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
010370-00031**
**suspended

&105.0014 5 lb/gal flowable concentrate
N-(mercaptomethyl)phthalimide S-(O,O-dimethyl phosphorodithioate)
(059201)
002724-00321

EPA Compendium of Acceptable Uses

N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
006601	--	aromatic petroleum distillate
081301	--	captan
063503	--	petroleum distillate
086803	--	xylene range aromatic solvent
014506	—	zineb

— Use EPA Acceptable Common/Chemical Name

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N-(MERCAPTOMETHYL)PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE)

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
035001	--	dimethoate
090301	--	methomyl
069001	--	pyrethrins

-- Use EPA Acceptable Common/Chemical Name

IV. BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Phosmet Standard

MRID	CITATION
00046189	McCabe, J.; Howell, A.; Jones, B.; et al. (1949?) Toxicity Studies with Rats: T-6304. (Unpublished study received May 20, 1980 under 476-2178; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:242478-D)
00046190	Jones, B.; Howell, A.; Barker, L. (1949?) Acute Rabbit Dermal Toxicity: T-6304. (Unpublished study received May 20, 1980 under 476-2178; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:242478-E)
00046191	Brookins, M. (1965?) Primary Skin Irritation: T-6304. (Unpublished study received May 20, 1980 under 476-2178; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:242478-F)
00046192	Brookins, M. (1965?) Ocular Irritation: T-6304. (Unpublished study received May 20, 1980 under 476-2178; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:242478-G)
00053821	Courtney, K.D. (1968) Teratological Investigation in Macaca mulatta of Captan, Imidan and Thalidomide. (Unpublished study including letters dated Jan 10, 1968 from K.D. Courtney to Geoffrey Woodard and Jan 12, 1968 from G. Woodard to A.B. Lindquist, received Jul 29, 1970 under unknown admin. no.; prepared by Bionetics Research Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:107817-L)
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00056850	Stauffer Chemical Company (19??) Frozen Storage Stability of Imidan on Apple Samples. (Unpublished study received Feb 10, 1964 under 6G0455; CDL:090497-O)
00056851	Stauffer Chemical Company (19??) Storage Stability of Imidan Extracts of Crop Samples. (Unpublished study received Feb 10, 1964 under 6G0455; CDL:090497-P)
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00056854	Stauffer Chemical Company (19??) Translocation of Imidan in Apples and Peaches. (Unpublished study received Feb 10, 1964 under 6G0455; CDL:090497-T)

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00056860	Batchelder, G.H.; O'Connor, M. (1965) Imidan Residue Data from Cattle Feeding Study at UC, Davis, RR-65-84. (Unpublished study received on unknown date under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-Z)
00056862	Batchelder, G.H.; O'Connor, M. (1965) Imidan Residue Data from Cattle Spray Study at USDA, Corvallis: RR-65-83. (Unpublished study received on unknown date under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-AB)
00056864	Ford, I.M. (1964) The Metabolism of Imidan C-14 in the Rat: Report No. 481. (Unpublished study received Feb 10, 1964 under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL: 090497-AE)
00056865	Ford, I.M.; Menn, J.J.; Meyding, G.D (1965) Metabolism of C14 N-(Mercaptomethyl)Phthalimide S-(O,O-Dimethylphosphorodithioate) (Imidan): Part I: Balance Study in the Rat. (Unpublished study received on unknown date under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-AF)
00056866	Menn, J.J.; McBain, J.B.; Adelson, B.J; et al. (1964) Degradation of N-(mercaptomethyl)phthalimide-S-(O,O-dimethyl) phosphorodithioate) (Imidan) in Soils. (Unpublished study received Feb 10, 1964 under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-AG)
00060625	Johansen, C.; Hutt, R. (1962) Bee Poisoning Investigations, 1962: Report No. 10617. (Unpublished study received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., submitted by Chemagro Corp., Kansas City, Mo.; CDL:092011-E)
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00063196	Dean, W.P. (1977) Acute Toxicity Studies in Rabbits and Rats: Study No. 153-051. (Unpublished study received Apr 18, 1978 under 476-1917; prepared by International Research and Development Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:234110-I)
00063197	Leong, B.K.J. (1977) Acute Inhalation Toxicity Study in Albino Rats--Saturated Atmosphere: Study No. 153-051. (Unpublished study received Apr 18, 1978 under 476-1917; prepared by International Research and Development Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:234110-J)

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00056865	Ford, I.M.; Menn, J.J.; Meyding, G.D (1965) Metabolism of C14 N-(Mercaptomethyl)Phthalimide S-(O,O-Dimethylphosphorodithioate) (Imidan): Part I: Balance Study in the Rat. (Unpublished study received on unknown date under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-AF)
00056866	Menn, J.J.; McBain, J.B.; Adelson, B.J; et al. (1964) Degradation of N-(mercaptomethyl)phthalimide-S-(O,O-dimethyl) phosphorodithioate) (Imidan) in Soils. (Unpublished study received Feb 10, 1964 under 6G0455; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090497-AG)
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00062649	Kidwell, C; Holme, I.; Horn, H.J.; et al. (1966) Imidan: Oral Compared to Dermal Administration to the Rabbit: Effect on Reproduction. (Unpublished study received Sep 20, 1967 under unknown admin. no.; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:140130-C)
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MRID	CITATION
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00067068	Stauffer Chemical Company (1980) Imidan 50-WP on Cottonseed: Summary of Crop Residue Data. (Compilation; unpublished study received Dec 31, 1980 under 476-1917; CDL:244021-B)
00067069	Adelson, B.J.; McKay, J.C.; Schwab, G.W. (1973) Determination of Residues of Imidan and Imidan Oxygen Analog. Method no. WRC 73-43 dated Jun 19, 1973. (Unpublished study received Dec 31, 1980 under 476-1917; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:244021-C)
00075425	Fogleman, R.W. (1960) Acute Oral Administration--Rats. (Unpublished study received Apr 8, 1976 under 476-2167; prepared by Hazleton Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233439-B)
00075426	Ford, I.M. (1962) Acute Oral Administration--Rats: Project 20-0240-32. Final rept. (Unpublished study received Apr 8, 1976 under 476-2167; prepared by Hazleton Nuclear Science Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233439-C)
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00076436	Lobdell, B.J.; Johnston, C.D. (1966) Imidan: Safety Evaluation by Two-year Feeding Studies in the Rat and the Dog. (Unpublished study, including letter dated Jul 21, 1966 from C.D. Johnston to A.B. Lindquist, received Sep 10, 1966 under 7F0523; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:090622-B)
00078567	McGuire, W.C.; McKay, J.; Meyding, G.D. (1969) Stability, Efficacy, Tissue Residues and Toxicity of Prolate Used in Cattle Dipping Vats. (Unpublished study received Feb 6, 1970 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:129280-D)
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00078570	Stauffer Chemical Company (1963) Imidan and Prolate Residues in Dairy Cows. (Compilation; unpublished study received Feb 6, 1970 under unknown admin. no.; CDL:129280-H)
00080552	Hill, R. (1963) 21 Day Subacute Dermal Toxicity Evaluation: Technical Report: Lab No. 2H7275. (Unpublished study received Aug 25, 1965 under 7F0523; prepared by Diablo Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:097514-S)
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00080556	Johnston, C.D. (1963) Imidan: An Evaluation of Safety of Imidan in the Rat and the Dog: Final Supplement. (Unpublished study received Aug 25, 1965 under 7F0523; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:097514-Y)
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V. FORMS APPENDICES

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner.

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

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PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________ Date ______________________

Guidance Document for ______________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ____________ Product Name ________________

Applicant's Name and Address ______________________________

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ____________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated ________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________

Date ____________ Title ______________________

EPA Form (April 1985)